PFEnex

Pfenex Inc.

Fiscal 2016 Annual Report

March 30, 2017

Dear Fellow Stockholders:

In 2016, Pfenex continued its momentum by further advancing our programs in product development. We made steady progress advancing our broad pipeline of biosimilar therapeutic candidates, therapeutic equivalent product candidates, and vaccine candidates, regained full rights to PF582 (biosimilar candidate to Lucentis®) and completed a worldwide license and option agreement with Jazz Pharmaceuticals (Jazz) that further demonstrates the versatility of our production platform. In addition to the progress within our development programs, we continued to strengthen the organization with the formation of our Scientific Advisory Board (SAB) that will provide technical guidance as we advance toward product commercialization.

This year, we saw increased clarity in the biosimilars market with the release of several important guidance documents that have further articulated the US Food & Drug Administration's (FDA) current thinking with regard to the biosimilar approval process in the United States. We also saw continued focus on domestic medical countermeasure infrastructure, as affirmed by our ongoing collaboration with the Biomedical Advanced Research and Development Authority (BARDA).

Our Product Candidates

Our product development programs continue to progress. In May, we announced positive top-line bioequivalence data in healthy subjects for PF708, our therapeutic equivalent candidate to Forteo®. In December, we initiated a pivotal clinical study for PF708, which will include an immunogenicity and pharmacokinetic assessment in osteoporosis patients. In July, we entered into a collaboration with Jazz on multiple hematology/oncology product candidates which includes an option for Jazz to negotiate a license for an Oncaspar® biosimilar candidate from Pfenex. Pfenex received upfront and option payments totaling $15 million and may be eligible to receive additional payments of up to $166 million based on the achievement of certain development, regulatory, and sales-related milestones, including up to $41 million for certain non-sales-related milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. In August, we announced positive results from the Phase 1/2 clinical study for PF582, our biosimilar candidate to Lucentis, and simultaneously regained full rights to the product. We continue to explore strategic options for the PF582 product. In December we received regulatory feedback for PF529, our biosimilar candidate to Neulasta®, and pursuant to that feedback we are currently evaluating a development plan for the product.

Finally, we continue to work closely with BARDA on Px563L, our recombinant protective antigen (rPA) anthrax vaccine candidate. In August we announced positive immunogenicity and safety data from the Day 70 analysis of Px563L in a Phase 1 clinical study. The results demonstrate tolerability and significant immunogenicity after only two doses of Px563L. Subsequent to the communication of the promising Phase 1 clinical data and the BARDA In Process Review (IPR) meeting, BARDA has authorized the opening of additional phases of the development contract in our $143.5 million advanced development contract in support of process optimization for the antigen and adjuvant. Our partnership with BARDA and ongoing communication with Congressional offices has emphasized the relevance of this initiative for US medical countermeasure support.

2016 Employee Additions and Scientific Advisory Board Development

In 2016, we added experienced professionals to the management team, including Steven Sandoval as our Chief Manufacturing Officer. Mr. Sandoval has over 25 years of commercial biopharmaceutical engineering and operations experience, specializing in commercial operations, facility design and licensure of large-scale biopharmaceutical commercial manufacturing facilities. He has extensive knowledge of cGMP biopharmaceutical engineering as well as significant first-hand experience preparing for and interfacing with the FDA and other global regulatory agencies during pre-licensure and biennial inspections of commercial cGMP biopharmaceutical manufacturing facilities. We also added Mayda Mercado as Vice President of Quality Assurance. Ms. Mercado is a quality and compliance leader with over 25 years of progressive leadership in the biopharmaceutical/pharmaceutical and health care industry, bringing a diverse and broad experience to the team.

In October, we announced the establishment of our inaugural Scientific Advisory Board (SAB) to assist Pfenex as we navigate process development and analytical similarity and move closer to product commercialization. SAB members include Greg Blank, Ph.D., a recognized global leader in bioprocess development; Matthew S. Croughan, Ph.D., an expert in biopharmaceutical, cell therapy, and biofuels process development; and Dennis Fenton, Ph.D., an industry pioneer, with over three decades of experience in biotechnology. Together, the vast industry experience of these three individuals will be invaluable as we advance our product pipeline.

Biosimilar Industry Overview

In 2016, the advancement of biosimilars in the US market was significant and the momentum was marked by additional biosimilar product approvals and further regulatory guidance from the FDA. We continued to see US approvals for biosimilars, with three approved in 2016 and one additional biosimilar approved in early 2015. There are currently at least 66 programs in the Biosimilars Biologic Product Development (BPD) program at the FDA. The increased scrutiny on drug pricing in the United States has highlighted the potential of biosimilars to be considered part of the solution.

Importantly, the FDA progressed the conversation within biosimilars, publishing final guidance on labeling in March, an important step in framing and paving the pathway for biosimilars marketing moving forward. We also saw additional clarity from the courts with the decision by the US Court of Appeals for the Federal Circuit decision in Amgen v. Sandoz, which determined that the decision of a biosimilar developer to engage in the patent dance with a reference product is optional, but that a biosimilar candidate must wait for FDA approval prior to providing 180-day market notification. In early 2017, the US Supreme Court agreed to hear the Amgen v. Sandoz case centering on these two particular provisions of the Biologics Price Competition and Innovation Act (BPCIA).

As the first biosimilars prepared to enter the US market, 2016 saw several insurance providers move toward adoption of biosimilars onto formularies, and in certain cases excluding the branded product in favor of its biosimilar. One payer has even gone so far as to establish a biosimilars-only tier providing lower out of pocket costs to patients and thus fostering biosimilar uptake.

Other key developments in the market included finalization of guidance from the Center for Medicaid and Medicare Services (CMS) on J-codes, which affirmed that all biosimilars of a reference product would share a J-code that was separate from the reference product J-code. The FDA also released guidance for biosimilars naming.

Moving forward, we expect to receive clarity and advancement on several important concepts in 2017. Specifically, we anticipate final guidance from the FDA on interchangeability as well as an ultimate decision on the patent dance and market exclusivity provisions from the Supreme Court. As well, we expect to see additional clarity around the Trump Administration’s impact on agencies and regulations, specifically as they relate to biosimilars market development.

We will continue to work closely with our industry and agency counterparts to advance understanding and education of biosimilars, encouraging market uptake and driving toward greater patient access to medicines through biosimilars approval and adoption.

Medical Countermeasures Overview

At the end of last year we saw continued support for medical countermeasures (MCMs) in Congress through the passage of the 21st Century Cures legislation. This important piece of legislation includes a specific incentive for developers of MCM’s to identified threats in the form of a Priority Review Voucher (PRV). The PRV can be applied to any other product requiring FDA approval; it provides a marketing application priority review, where FDA’s goal is to review such application within 6 months, instead of the traditional 10-month review period. The PRV can also be sold to another company, thereby providing an important financial incentive to MCM developers. In 2017, we look toward Congress for implementation of this legislation, including the appropriation

of funds to support BARDA, as well as providing resources to the BioShield Special Reserve Fund and the Strategic National Stockpile. These efforts could provide advanced funding for important programs such as Pfenex's anthrax vaccine program. Pfenex will continue to monitor and support these important policies and work with policymakers to provide medical countermeasures having the potential to protect the American public and our allies.

2017 and beyond

As we move into 2017, our strategy will focus on execution of our lead product development programs. We will be nimble in our response to evolving policies both domestically and globally, and will leverage our unique platform and approach to drive cost-effective development and production of biosimilar and medical countermeasure products. We continue to drive quality execution as the expectation of all stockholders and maintain our focus on educating the market as to the impact and benefit of biosimilars. We are focused on our commitment to maintain our competitive advantage by developing quality products efficiently and effectively. And, we will remain steadfast in our advocacy for the biosimilar and biodefense industries to be able to increase patient access to important therapies and provide the American public safety against certain biological threats.

I thank you for the confidence to which you have entrusted us at Pfenex.

Sincerely,

Patrick K. Lucy
Interim Chief Executive Officer, President, and Secretary, and Chief Business Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2016

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-36540

Pfenex Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-1356759**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

10790 Roselle Street
San Diego, California 92121
(Address of principal executive offices, including zip code)

858.352.4400
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value $0.001 per share	**NYSE MKT LLC**
(Title of each class)	**(Name of each exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act: Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based on the closing sale price of the Registrant's common stock on the last business day of its most recently completed second fiscal quarter, as reported on NYSE MKT, was approximately $169.3 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of March 6, 2017, there were 23,372,791 shares of the registrant's common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2016.

Pfenex Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2016

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As used in this Annual Report on Form 10-K, the terms "the Company," "we," "us" and "our" refer to Pfenex Inc. and its subsidiaries, unless the context indicates otherwise.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created thereunder and which involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our and our collaboration partners' ability to enroll patients in our clinical studies at the pace that we project;
- our expectations regarding the timing and the success of the design of the clinical trials and planned clinical trials of PF708, PF582 and our other product candidates, and reporting results from same;
- whether the results of our and our potential collaboration partners' trials will be sufficient to support domestic or global regulatory approvals for PF708 and PF582;
- our and our collaboration partners' ability to obtain and maintain regulatory approval of PF708, PF582 or our future product candidates, and the timing of such regulatory approvals;
- our reliance on third parties to conduct clinical studies;
- our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us;
- the benefits of the use of PF708, PF582 or any of our other product candidates;
- the rate and degree of market acceptance of PF708 and PF582 or any of our other product candidates;
- regulatory developments in the United States and foreign countries;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture PF708, PF582 and our other product candidates in conformity with regulatory requirements and to scale up manufacturing of PF708, PF582 and our other product candidates to commercial scale;
- our ability to successfully build a specialty sales force, or collaborate with third-party distributors, to commercialize our product candidates;
- our ability to compete with companies currently producing the reference products, including Forteo and Lucentis;
- our reliance on our collaboration partners' performance over which we do not have control;
- our ability to retain and recruit key personnel, including development of a sales and marketing function;
- our ability to obtain and maintain intellectual property protection for PF708, PF582 or any future product candidates;

- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- the sufficiency of our cash and cash equivalents and cash generated from operations to meet our working capital and capital expenditure needs;
- our expectations regarding the market size, size of patient populations, and growth potential for our product candidates, if approved for commercial use;
- our estimates of the expected patent expiration timelines for Forteo, Lucentis and other branded reference biologics;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;
- our ability to develop new products and product candidates;
- our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;
- our ability to successfully implement our planned remediation efforts with respect to our internal controls over financial reporting;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We cannot assure you that the results, events, and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K are based on information available to us on the date of this Annual Report on Form 10-K. We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

Pfēnex™ and Pfēnex Expression Technology® are our primary registered trademarks. This Annual Report on Form 10-K contains these trademarks and some of our other trademarks, trade names and service marks. Each trademark, trade name or service mark of any other company appearing in this Annual Report on Form 10-K belongs to its respective holder.

PART I

Item 1. *Business*

Overview

We are a clinical-stage biotechnology company engaged in the development of biosimilar and therapeutic equivalent products and other high-value and difficult-to-manufacture proteins. We leverage our protein production platform, *Pf*ēnex Expression Technology®, to produce complex proteins with higher accuracy and greater degree of protein purity, as well as speed and cost advantages. We use this technology to produce biosimilar candidates, therapeutic equivalent product candidates, as well as vaccine candidates. It is our goal to leverage our patented technology and our team's expertise in bioanalytical characterization to become a leading protein therapeutics company.

We are currently focused on several product candidates, however our two lead candidates are PF708, a therapeutic equivalent candidate to Forteo®, and PF582, a biosimilar candidate to Lucentis®.

Product Candidates

The following table summarizes certain information about our lead product candidates:

Product Candidate	Branded Reference Drug	Collaboration Partner	Indication
Biosimilars and Therapeutic Equivalents			
PF708 – Teriparatide	Forteo	Wholly-Owned	Osteoporosis
PF582 – Ranibizumab	Lucentis	Wholly-Owned	Macular edema or choroidal neovascularization conditions
Novel Vaccines			
Px563L – rPA based anthrax vaccine	N/A	U.S. Government Funded	Anthrax post-exposure prophylaxis

PF708 – Forteo

PF708 is a product candidate that is being developed as a therapeutic equivalent to Forteo (teriparatide), marketed by Eli Lilly for the treatment of osteoporosis patients at high risk of fracture. Forteo achieved approximately $1.4 billion in global product sales in 2015. The PF708 bioequivalence study, conducted in 70 healthy subjects, was completed in the second quarter of 2016 and met its primary objectives. The 90% confidence intervals of the area-under-the-curve (AUC) and maximum concentration (Cmax) geometric mean ratios of PF708 versus Forteo were within the 80-125% range required for concluding bioequivalence. We initiated an immunogenicity/pharmacokinetics clinical study in osteoporosis patients in the fourth quarter of 2016. We believe that this study, along with the positive bioequivalence study, should satisfy the filing requirements for PF708 through the 505(b)(2) regulatory pathway. The interim pharmacokinetic data from this study is expected in the second half of 2017 and the immunogenicity data is expected in the first half of 2018. We believe that the clinical program in the United States may be leveraged for regulatory filings in other geographies, such as the European Union.

PF582 – Ranibizumab

PF582 is a biosimilar product candidate to Lucentis (ranibizumab), indicated for the treatment of visual impairment due to neovascular, or wet, age-related macular degeneration (AMD), macular edema following retinal vein occlusion, choroidal neovascularization secondary to pathologic myopia, diabetic macular edema and diabetic retinopathy in patients with diabetic macular edema.

We have completed extensive bioanalytical similarity studies comparing PF582 to multiple lots of United States and European Union sourced Lucentis, as well as comparability studies between multiple lots of PF582 at the pilot scale and commercial scale. Based on our analytical and preclinical data package, the U.S. Food and Drug Administration, or FDA, granted us a Biosimilar Initial Advisory Meeting which was held in January 2014. We discussed the data that was generated prior to that date, our comparative clinical trial design and our strategy for the comparison of European Union and the United States licensed reference products. In the subsequent meeting minutes, the FDA indicated that our analytical data appear acceptable to support the development of PF582 as a biosimilar candidate to Lucentis. Similarly, we have had discussions with the European Union's Committee for Medicinal Products for Human Use, or CHMP, and Health Canada.

In the third quarter of 2016, we announced top-line results from the Phase 1/2 trial, which showed that PF582 was pharmacologically active and with a safety profile that was consistent with that of Lucentis. We enrolled a total of 25 VEGF-inhibitor naïve patients with neovascular AMD in the PF582 Phase 1/2 trial (13 received PF582, including one sentinel patient who received open label PF582, 12 received Lucentis). All patients received three monthly intravitreal injections. The primary endpoint of the study was safety and tolerability of PF582 compared to that of Lucentis. There were no clinically meaningful differences in adverse event profiles or intra-ocular pressure between PF582 and Lucentis. The efficacy and pharmacodynamic results indicated that there were no clinically meaningful differences in best corrected visual acuity or decreases in central retinal thickness between PF582 and Lucentis at any of the timepoints.

Vaccine Programs

Our *Pf*ēnex Expression Technology® is also well suited for vaccine development. We are developing Px563L, a novel anthrax vaccine candidate, in response to the United States government's unmet demand for increased quantity, stability and dose sparing regimens of anthrax vaccine. We initiated a randomized, placebo-controlled Phase 1a trial in healthy subjects in the second half of 2015 to investigate the safety and immunogenicity of Px563L, and we announced the interim analysis results in the second half of 2016. Findings indicated that the vaccine was well-tolerated, with the potential to afford immunogenicity protection against anthrax infection after only two injections (vs. three for the currently licensed anthrax vaccine product).

The development of Px563L is funded by the U.S. Department of Health and Human Services, through the Biomedical Advanced Research and Development Authority, or BARDA, in accordance with a cost plus fixed fee advanced development contract valued at up to approximately $143.5 million. In addition to the base period, BARDA has now exercised additional phases of the development contract effective January 2017, allowing for the continuing development of Px563L. The phase 2 study could initiate in 2018, provided the program continues to successfully advance with the support of BARDA.

The development of Px533, a prophylactic vaccine candidate against malaria infection, has been funded by Leidos, Inc., or Leidos, formerly Science Applications International Corporation, or SAIC, through its Malaria Vaccine Production and Support Services contract with the National Institute of Allergy and Infectious Diseases, or NIAID. Clinical trials for Px533 are controlled by NIAID.

Biosimilars Market Opportunity

A biosimilar is a biologic product that has been demonstrated to be highly similar to a biologic product that is already licensed, also known as a reference product. By definition, a biosimilar expresses no clinically meaningful differences when compared to a reference product in terms of safety, purity, and potency. In the next several years, a large number of blockbuster products are expected to lose patent protection, opening up the market for biosimilars.

It is our belief that this emerging biosimilar market will be significant as several biologic products reach patent expiry. According to IMS Health, by 2020, eight biologic products are expected to lose patent protection in the EU5 (France, Germany, Italy, Spain and the UK) and the US. Additionally, the abbreviated biosimilar

regulatory pathways established via legislation such as the Patient Protection and Affordable Care Act (ACA), coupled with an increasing mandate for lower drug costs by governments and private payers, has positively positioned the biosimilars market for rapid expansion.

It has been reported that the global biosimilars market is expected to reach $10.9 billion by 2021 from $3.4 billion in 2016, at a compound annual growth rate of 26% from 2016 to 2020. We expect the biologics market to shift toward biosimilars over the coming years, much like generic small molecule drugs, which currently accounts for an estimated 89% of the dispensed prescription small molecule drug market in the United States.

Our Strategy

Our strategy is to utilize our *Pf*ēnex Expression Technology® and our expertise in bioanalytical characterization and product development to become a leading protein therapeutics company focused on developing our own product candidates.

Our product candidate selection strategy focuses on products with large addressable markets, which are expected to be free of intellectual property barriers in major markets over our projected approval timelines, and for which our *Pf*ēnex Expression Technology ® enables efficient and large-scale manufacture of high-value and difficult-to-manufacture proteins. Our pipeline of product candidates and preclinical products under development includes wholly-owned programs, programs that are being developed in a joint venture with Strides Arcolab Limited (Strides Arcolab), and certain other products that are being developed in collaboration with Jazz Pharmaceuticals Ireland Limited (Jazz). In addition, we are also developing proprietary vaccine candidates that are being funded by the Department of Health and Human Services and the National Institutes of Health (NIH) within the United States government.

The key elements to implement our strategy include the following:

- ***Develop and obtain regulatory approval of PF708 and maximize its commercial potential.*** We are actively completing the necessary items that we believe will satisfy the filing requirements for the 505(b)(2) regulatory pathway in the United States to enable timeline regulatory approval as intellectual property protection and regulatory exclusivity for Forteo expire. In the fourth quarter of 2016, we initiated an immunogenicity/pharmacokinetics study in osteoporosis patients to compare the effects of PF708 and Forteo. The interim pharmacokinetic data from this study is expected in the second half of 2017 and the immunogenicity data is expected in the first half of 2018. We anticipate the results of this study will fulfill necessary filing requirements.
- ***Develop and obtain regulatory approval of PF582 and maximize its commercial potential.*** Following the termination of our collaboration with Hospira, Inc., a subsidiary of Pfizer Inc. (together, with Hospira, "Pfizer"), we are assessing the optimal development and commercialization strategy for PF582 to enable timely regulatory approval following the expected expiration of intellectual property protection and regulatory exclusivity for Lucentis.
- ***Develop vaccine programs primarily with non-dilutive government funding and other third-party grants.*** Using our *Pf*ēnex Expression Technology®, we are developing Px563L as a next generation anthrax vaccine candidate that we believe will address the limitations of the existing approved product including compliance, cost and potential fulfillment of the Strategic National Stockpile. We reported interim results of an ongoing Phase 1a trial in the second half of 2016 and anticipate its completion in the first half of 2017. The development of Px563L is funded through BARDA under a cost plus fixed fee advanced development contract valued at up to approximately $143.5 million. NIAID continues to evaluate our vaccine candidate, Px533, against malaria infection. Clinical development of Px533 is controlled and funded by NIAID.
- ***Continue to develop our pipeline of product candidates.*** We intend to continue developing a pipeline of additional biosimilar candidates, including PF529, a biosimilar candidate to Neulasta® and PF688, a

biosimilar candidate to Cimzia®. We have also developed PF530, a biosimilar candidate to Betaseron. We continue to evaluate new product candidates to add to our pipeline.

Biosimilars Background

The Biologics Price Competition and Innovation Act, or BPCIA, was enacted in 2010, creating an abbreviated approval pathway for biosimilar products, referred to as the "351(k) pathway". We believe the FDA's guidance to date provides the necessary clarity regarding approval requirements under the 351(k) pathway to permit the development of our biosimilar product candidates and the ultimate submission of applications for marketing approval for these product candidates. The first biosimilar in the United States, Zarxio® (filgrastim-sndz), was approved by the FDA in 2015.

Biosimilars Development and Challenges

Product development progresses differently with biosimilars than with innovative biologic candidates. This is a result of abbreviated development requirements for the approval of biosimilars as compared to innovative biologic products. Because a biosimilar product may reference existing information regarding the safety, purity and potency of a previously approved biologic product, a biosimilar product application emphasizes analytical characterization to demonstrate similarity between the biosimilar and the reference product, which regulators have already found to be safe and effective.

The development of proteins, such as biosimilars, requires several competencies which represent both challenges and barriers to entry. Due to their inherent complexity, proteins require the use of living organisms to efficiently produce them at large scale. Traditional techniques for protein production employ a trial and error approach to production organism, or production strain, selection and process optimization, which is inherently inefficient and typically produces suboptimal results. This historically inefficient process provides barriers to create or replicate complex proteins, adds significant time to market and results in the high cost of goods typical of biologic therapeutics. Together, these limitations pose significant hurdles for companies interested in entering the market with biosimilar and therapeutic equivalents to branded products.

Our Approach

Our patented protein production platform, *Pf*ēnex Expression Technology®, allows us to address hurdles to development and enable our product candidates. We believe our technology confers several important competitive advantages compared to traditional techniques for protein production, including the ability to produce complex proteins with higher accuracy and greater degree of protein purity, as well as speed and cost advantages. Our platform utilizes a proprietary high throughput robotically-enabled parallel approach, which allows the construction and testing of thousands of unique protein production variables in parallel, thereby allowing us to produce and characterize complex proteins while reducing the time and cost of development and long-term production.

We have replaced the traditional, trial and error approach to protein production with a simultaneous, parallel processing model that allows the construction and testing of thousands of unique protein production variables in parallel. This technology, which became our P*f*ēnex Expression Technology® was originated at Mycogen Corporation and further developed at The Dow Chemical Company , collectively, over a period of 20 years, and was assigned to us in the 2009 spinout to form the technology basis of our company. We have continued to improve the technology for the specific use in biopharmaceuticals development and manufacturing. We believe our platform delivers a significant competitive advantage for protein production, including higher accuracy, greater degree of protein purity, speed and lower costs.

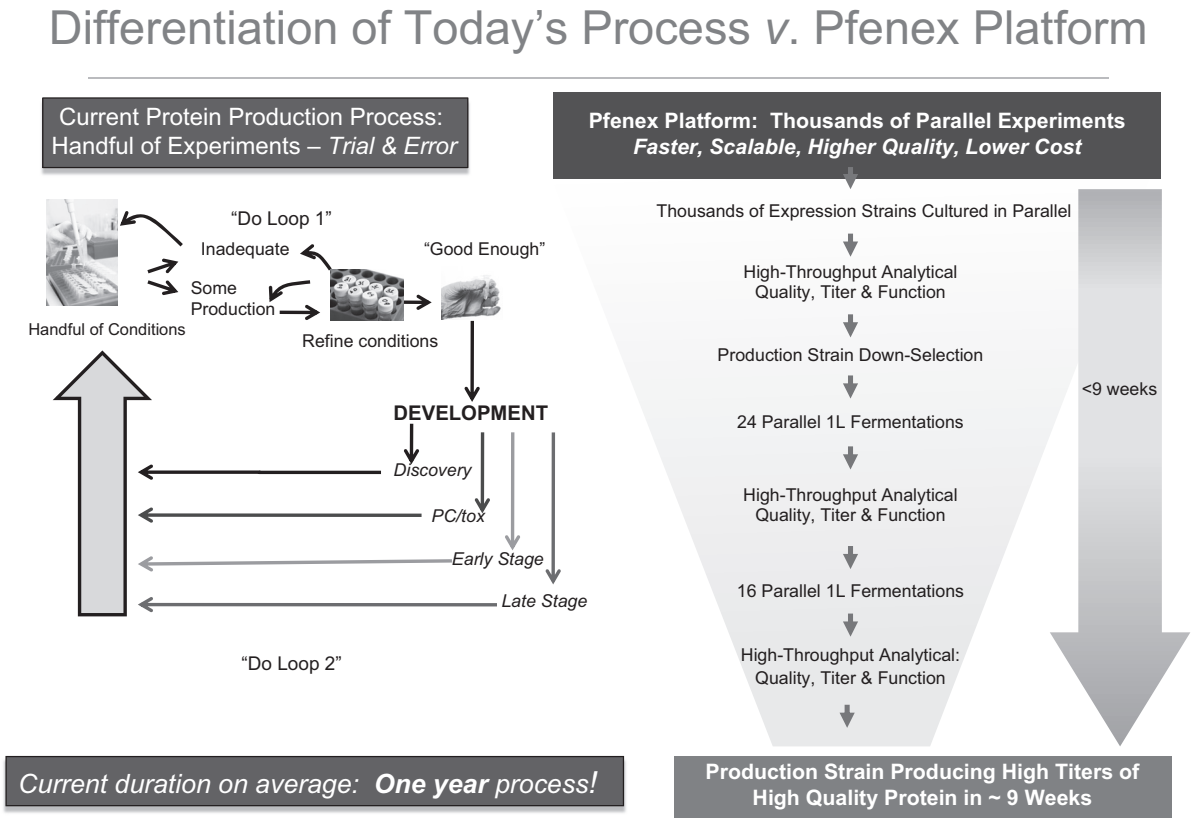
P*f*ēnex Expression Technology®

Protein Production Overview

Protein production is a fundamental activity necessary for biological drug development and manufacturing. The most common method of manufacturing therapeutic proteins involves the use of engineered microorganisms. Proteins produced using these organisms are referred to as recombinant proteins. Recombinant proteins are produced by inserting DNA, or a gene, that codes for the protein, into a cell which then acts as a protein production factory. Typically, this is accomplished by inserting DNA into an expression vector, which contains genetic control elements that can be used to turn the gene on and off.

Our platform is based on automated high-throughput screening of large libraries of novel, genetically engineered P. fluorescens bacterial expression strains. The libraries contain thousands of expression strains which are constructed from a large inventory of expression vectors, or genetic elements, incorporated into engineered P. fluorescens host strains. We then employ automated, robotically enabled parallel high-throughput screening, incorporating extensive bioanalytical testing, in order to select strains from the library which express the protein of interest at optimal yields, purity and potency. Extensive fermentation scouting experiments on the selected strains allows for the identification of a final production strain with further improvements in the yield of the active therapeutic protein.

Our patented P*f*ēnex Expression Technology® is capable of identifying a final production strain in approximately nine weeks compared to approximately one year or more in the typical case, if even possible, compared to the traditional trial and error approach as illustrated in the diagram below.



Our *Pf*ēnex Expression Technology® platform consists of three primary elements that, when combined, deliver a significant competitive advantage for protein production that differentiates us in the biopharmaceutical industry.

The three elements include:

- Robust Protein Production Organism
- Creation of Extensive Library of Protein Expression Variants
- Robotically Enabled High Throughput Screening

Robust Protein Production Organism

P. fluorescens has been used industrially where it has efficiently produced complex proteins. We exploit certain attributes of the *P. fluorescens* bacterium that enables us to rapidly identify the optimal strain for a specific protein of interest. The favorable attributes of the *P. fluorescens* bacterium include:

- Secretion of soluble protein into the bacterial periplasm, or the space between the inner and outer membrane in gram negative bacteria, resulting in increased recovery yields of properly folded protein
- *P. fluorescens* genome allows for modifications, including deleting protease genes, or nucleotides that provide instructions for synthesis of RNA into a specific protease, and inserting chaperone and/or disulfide bond isomerase genes, or nucleotides that provide instructions for synthesis of RNA into a specific chaperone or disulfide isomerase, which overall increase the quality and production of properly folded active full length proteins
- Selection of expression strains without the use of antibiotics
- High cell density fermentation due to its obligate aerobe growth nature, or bacterium that can only grow in the presence of oxygen, which improves the protein production for characterization, enables consistent scale-up and long-term low cost of goods

Creation of Extensive Library of Protein Expression Variants

We have developed an extensive toolbox of protein production variants that can be readily accessed for finding the best choice for manufacturing of a specific protein. This toolbox is continuously growing due to our ongoing research and development efforts. We construct libraries of thousands of unique expression strain variants by combining engineered *P. fluorescens* host strains with proprietary expression vectors. The engineered *P. fluorescens* strains have reduced expression of protein degrading enzymes and/or increased levels of folding elements while the expression vectors consist of plasmids with engineered genetic elements including promoters, ribosome binding sites and secretion leaders. Determining which of these variants will improve production of any particular protein cannot be determined from the amino acid sequence of the protein of interest. As a result, we employ the automated high throughput screening of a large library of the strain variants in order to select the strain that produces the protein of interest at optimal purity, yield and potency.

Robotically Enabled High Throughput Screening

Our high-throughput automation supports simultaneous, parallel evaluation of thousands of unique protein production alternatives, enabling rapid identification of the optimal production strain for the protein of interest. Our protein production technology employs rapid construction of protein production strains and testing thousands of unique variants evaluated through automated sample analysis to determine the titer, or quantity of the product per unit volume, of high quality protein each expression strain produces, which can then be analyzed through our high throughput analytical capacity. Our proprietary, robotically enabled automated high throughput screening process, along with our optimized production organism and toolbox of variants, as well as our expertise in analytical characterization, expedites the development of an optimal protein production engine from approximately one year in a typical case for traditional approaches, if at all possible, to approximately nine weeks with our P*f*ēnex Expression Technology®.

Reagent Proteins

Utilizing our P*f*ēnex Expression Technology®, we supply preclinical and cGMP-grade CRM197 to the biopharmaceutical and vaccine development community. We currently have supply agreements for the supply of cGMP CRM197.

Our Product Candidates

The development of our own portfolio of product candidates has been enabled by our successful history of meeting analytically rigorous client specifications of protein quality, yield and potency using our P*f*ēnex Expression Technology®. Our pipeline includes product candidates and preclinical products under development in various stages of development. Details of our pipeline are included below.

Therapeutic Equivalent, Biosimilar and Next Generation Candidates

PF708 – Teriparatide

One of our lead product candidates, PF708, is a peptide product candidate that is being developed as a therapeutic equivalent to the reference listed drug Forteo, an injectable prescription medicine marketed by Eli Lilly for the treatment of osteoporosis patients at high risk of fractures. Teriparatide is a shortened version of the naturally occurring parathyroid hormone (amino acids 1-34) that promotes bone growth. To date, we have demonstrated production of teriparatide in quantities that we believe predict a competitive cost of goods. Despite Forteo's status as a biologic peptide currently manufactured in *E. coli*, due to its size (less than or equal to 40 amino acids), it is considered a small molecule. As a result, we are developing PF708 pursuant to the Section 505(b)(2) regulatory pathway in the United States.

Market Overview

The global osteoporosis market represents a significant opportunity, with product sales that are estimated to grow to approximately $5.2 billion in the United States, Japan and the five major European Markets in 2021. Treatment with teriparatide is the only treatment approach that promotes bone growth currently available for the treatment of osteoporosis. According to the National Institutes of Health (NIH), it is estimated that approximately 44 million Americans either have osteoporosis or are at increased risk due to low bone mass (osteopenia). Forteo (marketed as Forsteo in Europe) is the only product currently approved that builds bone primarily by increasing the activity of osteoblasts (cells that deposit bone). Worldwide sales of Forteo were approximately $1.4 billion in 2015, according to Eli Lilly.

Development

We have performed an extensive bioanalytical comparative analysis of PF708 and Forteo. Based on what we believe to be equivalent results to date, we have not conducted preclinical in vivo studies for safety or efficacy purposes prior to initiating clinical investigation. We have also completed an initial assessment of the PF708 and Forteo injection pens, and we believe that the two injection devices are functionally equivalent. We completed a pharmacokinetic bioequivalence study in healthy subjects in the first half of 2016, and we initiated a comparative immunogenicity/pharmacokinetics study in osteoporosis patients in the fourth quarter of 2016. The interim pharmacokinetic data from this study is expected in the second half of 2017 and the immunogenicity data is expected in the first half of 2018.We anticipate that the study results will support the potential licensure of PF708 under the Section 505(b)(2) regulatory pathway in the United States.

PF582 – Ranibizumab

PF582, our other lead product candidate, is a biosimilar product candidate to Lucentis (ranibizumab), indicated for the treatment of visual impairment due to neovascular, or wet, age-related macular degeneration (AMD), macular edema following retinal vein occlusion, choroidal neovascularization secondary to pathologic myopia, diabetic macular edema and diabetic retinopathy in patients with diabetic macular edema.

Market Overview

Lucentis achieved approximately $3.6 billion in global product sales in 2015. By the second quarter of 2018, markets with 2015 Lucentis sales of approximately $530 million are expected to lose patent protection, and become available to biosimilars. By the second quarter of 2020, markets with an additional $1.8 billion in 2015 Lucentis sales are expected to lose patent protection and become available for biosimilars, and after January 2022 markets with an additional $1.2 billion in 2015 sales are expected to also lose patent protection.

Given the characteristics of the patient populations for each of its approved indications, we believe ranibizumab has attractive long-term growth prospects. In addition, we believe, the market is underpenetrated for the approved indications allowing future growth opportunities particularly for lower cost biosimilars.

- Wet AMD—Age-related macular degeneration, or AMD, is the leading cause of severe vision loss in people over age 60, and it impacts approximately 30-50 million people worldwide. AMD occurs when the center of the retina, known as the macula, deteriorates. In the United States, approximately 15 million people suffer from AMD. Wet AMD accounts for about 10% of all cases of AMD and about 600,000 new cases of wet AMD are diagnosed each year globally.
- Diabetic Macular Edema—Diabetic macular edema, or DME, is the leading cause of blindness in young adults in developed countries. The global prevalence of DME is approximately 21 million people. Worldwide, 285 million adults suffer from diabetes, and the number of adults who suffer from diabetes is projected to increase by 69% in developing countries and 20% in developed countries from 2010 to 2030. Approximately 28% of patients with type 2 diabetes and 12% of patients with type 1 diabetes will develop DME.
- Retinal Vein Occlusion—Retinal vein occlusion, or RVO, is the blockage of the small veins that carry blood away from the retina, potentially causing glaucoma and loss of vision. RVO affects more than one million people in the United States and 16.4 million people globally. In the United States, approximately 193,000 new cases of RVO are diagnosed each year.
- Myopic Choroidal Neovascularization—Myopic choroidal neovascularization, or mCNV, is a complication of severe near-sightedness that can lead to blindness. In mCNV, new, abnormal blood vessels grow directly into the retina. These vessels may break and leak blood or fluid into the retina, which can cause irreversible central vision loss. mCNV affects approximately 41,000 people in the US, and it most commonly affects people between ages 45 and 64. It is estimated that mCNV exists in 5%-10% of highly myopic patients.

Development

We have completed extensive bioanalytical similarity studies comparing PF582 to multiple lots of United States and European Union sourced Lucentis, as well as comparability studies between multiple lots of PF582 at the pilot scale and current Good Manufacturing Practice, or cGMP, commercial scale. We have also completed a preclinical study using an animal model that demonstrated, when injected into animal eyes, PF582 and Lucentis yielded similar tolerability and pharmacological profiles. Based on our analytical and preclinical data package, the FDA granted us a Biosimilar Initial Advisory Meeting which was held in January 2014 to discuss the data we had generated to date, our comparative clinical trial design and our strategy for the comparison of European Union and United States licensed reference products. In the subsequent meeting minutes, the FDA indicated that our analytical data appear acceptable to support the development of PF582 as a biosimilar candidate to Lucentis.

In the third quarter of 2016, we announced the results of a randomized Phase 1/2 trial in patients with wet AMD. We believe that positive results from a future global comparative clinical trial should provide sufficient data to seek and secure marketing approval in our target markets.

Px563L

Px563L is a novel anthrax vaccine candidate based on a recombinant modified form (mutant) of the protective antigen from *Bacillus anthracis* (anthrax). We are developing Px563L in response to the United States government's unmet demand for increased quantity, stability and dose sparing regimens of anthrax vaccine. We believe that Px563L can address each of these demands. We initiated a randomized, placebo-controlled Phase 1a trial in healthy subjects in the second half of 2015 to investigate the safety and immunogenicity of Px563L, and we announced the interim analysis results in the second half of 2016. Findings indicated that the vaccine was well-tolerated, with the potential to afford immunogenicity protection against anthrax infection after only two injections (vs. three for the currently licensed anthrax vaccine product). The development of Px563L is funded by the U.S. Department of Health and Human Services (HHS) through BARDA under a contract providing up to $143.5 million in funding.

Market Overview

In October 2001, letters contaminated with anthrax spores were delivered to government officials and members of the media in the United States. As a result of these attacks, 22 people became infected with anthrax and five people died. In response to this and other terrorist attacks around the world, the biodefense market has grown dramatically. In December 2016 the Centers for Disease Control (CDC) signed a procurement contract for BioThrax valued at up to $911 million to supply to the Strategic National Stockpile that represents approximately 29.4 million doses through September 2021. The federal government spends billions of dollars in biodefense through HHS, CDC, NIAID and Office of Public Health Preparedness and Response. In 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act, or PAHPRA, which was originally passed in 2006 to improve the United States' public health and medical preparedness and response capabilities for emergencies, authorized $2.8 billion for the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. If successful with clinical development, we believe we may be able to enter into a procurement relationship with the US federal government to supply a next generation recombinant protective antigen (rPA) based anthrax vaccine to the Strategic National Stockpile.

Development

In preclinical animal studies, Px563L has resulted in a greater immune response than the only available anthrax vaccine, BioThrax, and has the potential to provide longer protective immunity with fewer vaccinations. Through the application of our P*f*ēnex Expression Technology® we have developed a robust production strain for manufacturing that has demonstrated an ability to produce large amounts of mutant recombinant protective antigen, or mrPA.

In August 2016, we announced positive immunogenicity and safety data from Day 70 analysis of the Px563L anthrax vaccine study. The randomized, double-blind, placebo-controlled Phase 1a study enrolled three cohorts in a dose-escalating manner (10 mcg, 50 mcg and 80 mcg of antigen). Within each cohort, subjects received Px563L, RPA563 or placebo in an 8:8:2 ratio. Subjects were administered two doses of vaccine or placebo 28 days apart. Interim results indicated that the vaccine was well-tolerated, with the potential to afford immunogenicity protection against anthrax infection after only two injections (vs. three for the currently licensed anthrax vaccine product). Immunogenicity was assessed by toxin-neutralizing antibody (TNA) expressed as 50% neutralizing factor (NF50), with a threshold value ≥0.56 correlating with significant survival in animal models of anthrax infection. On Day 70, 100% of Px563L subjects at the 10 mcg and 80 mcg dose levels achieved a TNA NF50 ≥0.56, and 87.5% at the 50 mcg dose level achieved the target threshold. An additional success criterion for assessing anthrax vaccine immunogenicity is for the lower confidence limit (LCL), or the lower bound of 95% confidence interval, of the percentage of subjects who met or exceeded the TNA NF50 threshold of 0.56, to be greater than or equal to 40%. On Day 70, all doses of Px563L exceeded this threshold, which was established by the currently licensed anthrax vaccine for the indication of post-exposure prophylaxis.

In addition, we have developed a production process for the large scale manufacturing of bulk mrPA. We announced positive interim results from a Phase 1a study in healthy subjects in the second half of 2016, and we anticipate study completion in the first half of 2017.

Additional Products Under Development

Given the Jazz collaboration and our recent pipeline review, we have decided to advance the hematology assets that are part of the Jazz collaboration ahead of the PF530 biosimilar Betaseron opportunity. The expenses associated with PF530 will be reduced as part of the portfolio re-alignment. We completed a Phase 1 trial of PF530, a biosimilar candidate to Betaseron, in 2015 which enrolled 12 healthy subjects. Based on the analysis of the trial PK and PD parameters, no meaningful differences between PF530 compared to the reference compound were observed. Potential strategic opportunities for the PF530 program will be explored, given the successful advancement of PF530 and the positive regulatory feedback.

We also have a number of preclinical products under development. We are currently in process development for PF529, a peg-filgrastim biosimilar candidate to Neulasta, as well as for PF690 pegaspargase, a biosimilar candidate to the reference product Oncaspar. Regulatory feedback for PF529 was received in 2016 and supported the feasibility of development under the 351(k) biosimilar pathway. We continue to evaluate the potential resource requirements and timeline for development. Additional products in process development include PF444-human growth hormone, and PF688-certolizumab-pegol, which are being developed as biosimilars of Genotropin, and Cimzia, respectively.

Collaborations, Joint Development, and Licenses

Jazz Pharmaceuticals

In July 2016, we entered into a development and license agreement, or the Jazz Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, for the development and commercialization of multiple early stage hematology product candidates. The agreement also includes an option for Jazz to negotiate a license for a recombinant pegaspargase product candidate with us. Under the Jazz Agreement, we received an upfront and option payment totaling $15 million in July 2016 and may be eligible to receive additional payments of up to $166 million based on achievement of certain research and development, regulatory and sales related milestones, including up to approximately $41 million for certain non-sales-related milestones. The total milestones are categorized as follows: $7 million are based on achievement of certain research and development milestones; $34 million for certain regulatory milestones; and $125 million for sales-related milestones. For the non-sales-related milestones, we conducted an evaluation of whether they will be recorded using the milestone method and as a result of this evaluation, we estimate approximately $7 million of these non-sales-related milestones are deemed to be substantive. We may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. We and Jazz will both be contributing to the development efforts. Unless terminated earlier, the Jazz Agreement will continue on a product-by-product basis for as long as Jazz is commercializing or having commercialized the products under the Jazz Agreement.

Pfizer

In February 2015, we entered into a development and license agreement with Pfizer for the development and commercialization of PF582. Under the terms of the development and license agreement, in March of 2015 we received a non-refundable license payment of $51 million on receipt of antitrust approval. We regained the full rights to PF582 following Pfizer's strategic review of the current therapeutic focus of its biosimilar pipeline. To that effect, in August 2016, we entered into a termination agreement, pursuant to which the development and license agreement was terminated and all rights to PF582 were returned to us.

Strides Arcolab

In December 2012, we entered into a Joint Development & License Agreement, or JDLA, with Strides Arcolab, to develop biosimilar products according to development plans to be mutually agreed upon by us and Strides Arcolab. Under such development plans, we will generally be responsible for establishing and characterizing a research cell bank of the protein production strain and developing a manufacturing process and analytical methods, while Strides Arcolab will generally be responsible for developing master and working cell banks for the applicable protein production strain, developing a formulation for the applicable biosimilar product, manufacturing the biosimilar for Phase 1 trials, conducting preclinical and Phase 1 trials and managing regulatory matters. Each of Strides Arcolab and us will bear our own costs for the aforementioned development activities. Each of Strides Arcolab and us must use commercially reasonable efforts to accomplish the objectives set forth in the development plan for each biosimilar product and certain milestones set forth in the JDLA. Except pursuant to the JDLA during its term, neither we nor Strides Arcolab may develop, manufacture, supply or commercialize any product that is being or has been developed under the agreement or assist any third party to do the same.

In March 2013, we entered into a joint venture agreement, or JVA, with Strides Arcolab to form a joint venture company, or JV, to develop and commercialize biosimilar products developed under the JDLA that have completed Phase 1 trials. Under the terms of the JVA, when formed, we will own a 49% equity interest in the JV, while Strides Arcolab will own a 51% equity interest in the JV. Both we and Strides Arcolab will have equal board representation and equal voting rights.

In February 2015, we notified Strides Arcolab that we were removing PF530 Interferon beta-1b, PF726 PEGylated Interferon beta-1b and PF529 PEGylated filgrastim from the JDLA. We intend to independently advance these candidates as wholly owned products.

Currently there are two biosimilar candidates for development under the JDLA and potential further development and commercialization by the JV:

- PEGylated interferon alpha-2a (a biosimilar candidate to Roche's Pegasys); and
- Human growth hormone (a biosimilar candidate to Pfizer's Genotropin).

After transfer of a biosimilar product to Strides Arcolab, Strides Arcolab will be responsible for manufacturing such biosimilar product, preparing and filing all regulatory filings and conducting the Phase 1 study. Upon successful completion of the first Phase 1 trial for each biosimilar candidate, the product will transfer to the JV and the JV will be responsible for all regulatory filings and approvals, clinical trials, commercialization strategies and distribution of the applicable biosimilar product upon approvals. Also transferred to the JV are all associated data, rights and assets, including any inventions developed by us or Strides Arcolab under the JDLA and all intellectual property rights therein. The JDLA will continue on a biosimilar product-by-biosimilar product basis until successful completion of the first Phase 1 trial for such biosimilar product. Either we or Strides Arcolab may terminate the JDLA in its entirety for the other party's insolvency, or in its entirety or with respect to the applicable biosimilar product for the other party's material breach of the JDLA. In addition, if the JVA is terminated in its entirety, the JDLA will automatically terminate.

The JVA will remain in effect so long as there is at least one biosimilar product under development or commercialization by the JV. If the JV fails to initiate the first commercial sale of a biosimilar product within the timeframe set forth in the plan for such biosimilar product, either we or Strides Arcolab may terminate the JVA with respect to such biosimilar product upon notice to the other party. Beginning March 7, 2018, either we or Strides Arcolab may offer to sell our or Strides Arcolab's entire equity interest in the JV to the other party, at which time the other party must either buy the first party's entire interest in the JV or sell to the first party such other party's entire interest in the JV. In addition, if either we or Strides Arcolab materially breaches the JVA or become insolvent and fail to cure such breach or insolvency within a specified period of time, the other party

may require the breaching or insolvent party to buy such other party's entire equity interest in the JV or to sell such breaching or insolvent party's entire equity interest in the JV to such other party.

The Dow Chemical Company

On November 30, 2009, we entered into a series of agreements with Dow Global Technologies LLC and/or The Dow Chemical Company, or collectively, Dow, including a technology assignment agreement, a technology licensing agreement, and a grant-back and technology license agreement. Under the technology assignment agreement, Dow assigned to us certain patents, know-how and trademarks relating to our P*f*ēnex Expression Technology®. Under the technology licensing agreement, Dow granted us exclusive licenses to exploit certain patents relating to RNA viruses and oral immunization methods (each of which were subsequently terminated), and certain amended recombinant cells, and a non-exclusive license to exploit certain patents relating to production and isolation techniques for peptides and proteins made using our P*f*ēnex Expression Technology®. Under the grant-back and technology license agreement, we granted to Dow exclusive and non-exclusive licenses under certain patents and know-how relating to our P*f*ēnex Expression Technology® to use certain biological materials to make, use and commercialize products in certain fields of use that do not include human therapeutics.

The U.S. Department of Health and Human Services

In July 2010, we entered into a contract with BARDA, a division of the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, to develop a production strain and process for the production of bulk recombinant Protective Antigen, or rPA, from anthrax. Under the contract, we agreed to provide protein production and process development services to BARDA. The contract was amended several times to advance development of the product, and BARDA exercised options to provide additional funding and extend the term of the contract. In December 2014, we filed the investigational new drug, or IND, application for Px563L. BARDA extended the contract in December 2014 and provided additional funding, increasing the total contract to $25.2 million. A total of $24.8 million had been recognized as revenue under the development contract, which was completed in August 2015.

In August 2015, we entered into a five-year, cost plus fixed fee contract valued at up to $143.5 million with BARDA for the advanced development of Px563L, which is a mutant recombinant protective antigen anthrax vaccine. The contract consists of a 30-month base period with total funding up to $15.9 million that will fund activities related to cGMP manufacturing of drug product and a Phase 1a clinical study. In addition to the base period, there are eight option periods, with potential additional funding of up to $127.6 million that will fund activities including completion of a Phase 1b clinical study, a Phase 2 clinical study and non-clinical efficacy studies, as well as manufacturing technology transfer and optimization, process and analytical method validation and consistency lot manufacture. In addition to the base period, BARDA has exercised additional phases of the development contract effective January 2017, allowing for the continuing development of Px563L. The phase 2 study could initiate in 2018, provided the program continues to successfully advance with the support of BARDA. We believe the successful completion of the activities under this contract could lead to a procurement contract for supply of Px563L to the Strategic National Stockpile.

As the prime contractor, we are responsible for performing activities under a research plan proposed by us and accepted by BARDA. We are also obligated under the contract to satisfy various federal reporting requirements, including technical reporting with respect to our development activities, reporting with respect to intellectual property and financial reporting. In addition, certain technical documents and our clinical trial protocols may be reviewed by BARDA prior to their finalization and/or submission.

Under standard government contracting terms, the government receives only limited rights for government use of certain of our pre-existing data and certain data produced with non-federal funding, to the extent such data are required for delivery to BARDA under the project. The United States government receives unlimited rights to

use and disclose new data first produced under the project with BARDA funding. If the product is successfully developed and achieves marketing authorization, we would have the commercial rights to the anthrax vaccine; provided that the United States government is entitled to a nonexclusive, worldwide, royalty-free license to practice or have practiced any patent on an invention that is conceived or first reduced to practice under the project, and may obtain additional rights if we do not elect to retain ownership of a subject invention or if we do not satisfy certain disclosure and patent prosecution obligations with respect to a subject invention. Our contract with BARDA does not entitle the government to any sales royalties or other post-commercialization financial rights.

BARDA is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond current year amounts allotted from Congressionally approved annual appropriations.

The National Institute of Allergy and Infectious Diseases (NIAID)

In September 2012, we entered into a contract with NIAID for the development of a next generation anthrax vaccine. Under the contract, which was amended in April 2013 and November 2013, we have agreed to provide services to NIAID for approximately 25 months under a cost plus fixed fee contract with a total value of approximately $2.2 million. In addition to the base period, NIAID has 13 options to extend the term of the contract, with payments totaling approximately $22.9 million. NIAID exercised an option effective January 2015 and another effective May 2016.

As the prime contractor, we are responsible for performing activities under a research plan proposed by us and accepted by NIAID. We are also obligated under the contract to satisfy various federal reporting requirements, including technical reporting with respect to our development activities, reporting with respect to intellectual property and financial reporting.

Under standard government contracting terms, the government receives only limited rights for government use of certain of our pre-existing data and certain data produced with non-federal funding, to the extent such data are required for delivery to NIAID under the project. The United States government receives unlimited rights to use and disclose new data first produced under the project with NIAID funding. If an anthrax vaccine is successfully developed and achieves marketing authorization we would have the commercial rights to the anthrax vaccine; provided that the United States government is entitled to a nonexclusive, worldwide, royalty-free license to practice or have practiced any patent on an invention that is conceived or first reduced to practice under the project, and may obtain additional rights if we do not elect to retain ownership of a subject invention or if we do not satisfy certain disclosure and patent prosecution obligations with respect to a subject invention. Our contract with NIAID does not entitle the government to any sales royalties or other post-commercialization financial rights.

NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond current year amounts allotted from Congressionally approved annual appropriations.

Customers

As of December 31, 2016, we had generated only limited revenue from government contracts, service agreements, collaboration agreements, and reagent protein product sales. Our total revenue was $60.2 million, $9.6 million and $10.6 million in 2016, 2015 and 2014, respectively. In 2016, a significant portion of our revenue was derived from recognizing $45.8 million in revenue upon termination of the Pfizer agreement in August 2016, in addition to revenue derived from development and license agreements. In 2015 and 2014, a significant portion of our revenue was derived from developing proprietary vaccine candidates for government agencies.

For the year ended December 31, 2016, Pfizer accounted for more than 10% of our revenue. For the year ended December 31, 2015, BARDA and Pfizer each accounted for more than 10% of our revenue. For the year ended December 31, 2014, BARDA, NIAID and Boehringer Ingelheim International GmbH each accounted for more than 10% of our revenue.

Government Regulation

Government authorities in the European Economic Area, at European Union and national Member State level, and in United States, at the federal, state and local level, extensively regulate, among other things, the research, development, testing, manufacturing, labeling, packaging, promotion, advertising, storage, distribution, marketing, post-approval monitoring and reporting, and export and import of drugs and biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

European Economic Area Regulation

In the European Economic Area, or EEA, comprising the European Community (European Union) plus Iceland, Liechtenstein and Norway, the information that must be submitted to the European Medicines Agency, or EMA, or to the competent authorities in the relevant European Union Member States varies depending on whether the biological medicinal product is a new product, whose quality, safety and efficacy has not previously been demonstrated in humans or a product whose known biological active substance and certain other properties are similar to those of a previously authorized (reference) biological medicinal product. The European Directive 2001/83/EC as amended defines a medicinal product as any substance or combination of substances:

- presented as having properties for treating or preventing disease in human beings; or
- which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Directive 2001/83/EC as amended further defines the category of biological medicinal products as:

- a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterization and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.

Examples of biological medicinal products include recombinant proteins, monoclonal antibodies, vaccines, and products derived from human blood or plasma.

Approval of New Biological Medicinal Products

In the EEA, all medicinal products (biological or not) can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MA:

The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the CHMP of the EMA, is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as medicinal products derived from certain biotechnology processes (including biotechnology-derived proteins such as the ones we make), orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes and auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the

Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

More concretely, the requirements for centralized marketing authorization of a new biological medicinal product in the EEA generally include but are not limited to:

- submission of the results of pharmaceutical (physico-chemical, biological or microbiological) tests and preclinical (toxicological and pharmacological) tests through laboratory tests and animal studies in compliance with Good Laboratory Practice, or GLP;
- submission to the competent authorities of a Clinical Trial Application, or CTA, which must become effective before human clinical trials may begin and must include the protocol, Investigator's Brochure, Investigational Medicinal Product-related data, and independent Ethics Committee approval;
- submission of the results of adequate and well-controlled clinical trials to establish the quality, safety and efficacy of the product for each indication;
- a statement to the effect that clinical trials carried outside the European Union meet the ethical requirements of Directive 2001/20/EC;
- submission of an application for marketing authorization to the EMA or to the competent authorities of the relevant EU Member States;
- establishment of the applicant in the EEA;
- description of the qualitative and quantitative particulars of all constituents of the medicinal product;
- evaluation of the potential environmental risks posed by the medicinal product;
- description of the manufacturing method, description of the control measures employed by the manufacturer, and a document showing that the manufacturer is authorized in his own country to produce medicinal products;
- a summary of product characteristics, therapeutic indications, adverse reactions, dosage, pharmaceutical form, route of administration and expected shelf life;
- additional information for specific classes of medicinal products, such as a Vaccine Antigen Master File documentation for vaccine products;
- a summary of the pharmacovigilance system, the risk management plan describing the risk-management system, and proof that the applicant has the services of a qualified person responsible for pharmacovigilance as well as the necessary means for fulfilling the EU pharmacovigilance obligations including the notification of any adverse reaction suspected of occurring either in the EEA or in a third country; and
- review by EMA's CHMP or the competent authorities in the relevant European Union Member States and approval of the marketing authorization application.

Preclinical tests include laboratory evaluations of the product's structure, purity and biological activity, as well as animal studies to determine toxicity and pharmacology. An Investigational Medicinal Product (IMP) sponsor must submit a CTA to the competent authority prior to initiation of human clinical trials. The application process to perform a clinical trial in the EEA is governed on a country-by-country basis. A sponsor must apply in

each country in which it intends to conduct any part of a human clinical trial. While the process is similar in most countries, additional materials may be required in certain instances. For example, in many, but not all European countries, a sponsor must submit a copy of the insurance coverage obtained to cover the clinical study. Australia and New Zealand adhere to EMA guidelines with respect to the regulation of IMPs and clinical trials.

Assuming successful completion of the required clinical testing, and having met all criteria set forth by Directive 2001/83/EC and Regulation (EC) No 726/2004, the applicant may choose to proceed with submission of marketing authorization application. If the application is accepted for review in the Centralized Procedure, within 210 days (excluding clock stops), the EMA's CHMP will issue an opinion on whether the conditions for granting market authorization are satisfied. During the review period, the scientific committees will review the scientific data, may request for independent testing of the medicinal product, its starting materials, or other constituent materials, may request supplemental information from the applicant, may request for proof of cGMP compliance of the manufacturer, and may request for said manufacturing facilities to be inspected.

Accelerated Review

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA's CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

Approval of Similar Biological Medicinal Products

Similar biological medicinal product applications of medicinal products authorized via the Centralized Procedure have automatic access to the Centralized Procedure. Similar biological medicinal products that do not fall under the mandatory scope can, at the request of the applicant, be accepted for consideration under the Centralized Procedure, when the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or when the applicant shows that the granting of a Community authorization for the medicinal product is in the interest of patients at European Union level.

A similar biological medicinal product, also known as a biosimilar, is a product that is similar to a biological medicine that has already been authorized, the so-called "reference medicinal product." The active substance of a similar biological medicinal product is a known biological active substance and similar to the one of the reference medicinal product. A similar biological medicinal product and its reference medicinal product are expected to have the same safety and efficacy profile and are generally used to treat the same conditions.

The similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy. The dosage and route of administration should be the same while deviations in formulation or inactive substances require justification or further studies. Intended changes to improve efficacy are not compatible with a biosimilarity approach. The minimum expectation of data supplied with the application will include pharmaceutical, chemical, and biological preclinical data, as well as bioequivalence and bioavailability (bodily distribution and concentration) clinical data. The type and amount of additional information, such as toxicological and other preclinical and clinical data, is determined on a case-by-case basis. Unlike in the United States, the directives and guidelines governing the EEA do not explicitly provide for the designation of interchangeability of similar biological medicinal products, nor does the EMA submit an opinion on whether a biosimilar can be used interchangeably with its reference product.

EMA guidelines suggest that clinical trials comparing a biosimilar candidate to a reference medicinal product be designed such that they will demonstrate not only similar efficacy but also similar clinical outcome

with respect to safety. Clinical trials designed to establish the expectation of equivalent clinical outcomes for any one patient require a sufficiently large number of patients in the study such that certain statistical measures are satisfied. As such, equivalence trials are usually more expensive and longer in duration than non-inferiority trials that may be employed in other medicinal product categories. The EMA recommends engaging in discussions with regulatory authorities if the use of a non-inferiority design is being considered. If a reference product is approved for more than one therapeutic indication, the efficacy and safety of the biosimilar has to be justified or, if necessary, demonstrated separately for each of the claimed indications. This may include a review of clinical experience and available literature data, or the execution of further non-clinical or appropriate clinical studies.

The EMA provides additional specific guidance and requirements for products being developed as biosimilar candidate to EEA-authorized Interferon-beta 1a or 1b and Interferon-alpha 2a or 2b. The guidance outlines specific types of preclinical data and clinical studies required to support the claim of biosimilarity. Additionally, the guidelines provide specific considerations for assessing clinical safety and for post-authorization pharmacovigilance monitoring.

European Union legislation provides (with respect to reference products for which a marketing authorization was applied for after October 30, 2005 under the Decentralized, Mutual Recognition and national procedures, or after November 20, 2005, for products authorized under the Centralized Procedure) for an eight-year period of data protection and ten-year period of market exclusivity for medicinal products which received marketing authorization in accordance with, respectively, Directive 2001/83/EC as amended or Regulation (EC) No 726/2004 as amended. The provisions also state that if, during the first eight years of authorization, the holder obtains an authorization for one or more new therapeutic indications which are deemed to have significant clinical benefit as compared to existing therapies, the original market exclusivity can be extended to a maximum of 11 years. The data and market exclusivity periods start from the date of the initial authorization, which for reference medicinal products authorized through the Centralized Procedure is the date of notification of the marketing authorization decision to the marketing authorization holder of the reference product.

Post-Approval Requirements

Once granted, initial marketing authorization of a medicinal product is valid for five years. The authorization may be renewed after five years on the basis of a reevaluation of the risk-benefit balance. At that point, once renewed, the marketing authorization is valid indefinitely or, if justified on grounds of pharmacovigilance, may be restricted to an additional five-year authorization period.

Marketing authorization holders are required to maintain a pharmacovigilance system and to maintain detailed records of all suspected adverse reactions in the EEA or in a third country. Serious suspected adverse reactions are to be communicated to the appropriate EEA regulatory authorities no later than 15 days after receipt of the information. EEA regulations require periodic safety reporting leading up to and following market authorization, based on a defined schedule, for as long as the product is marketed, or when immediately requested by regulatory authorities. An increase in incidents of adverse events or any cause for a change in opinion by the EMA pertaining to the risk-benefit balance may lead to suspension, variation, or revocation of marketing authorization and would severely impact our business.

EEA regulations also stipulate that regulators, such as the Competent Authorities of the EEA Member States, independently or coordinated by the EMA, may carry out repeated or unannounced inspections of the medicinal product manufacturer or at the premises of the marketing authorization holder, regarding compliance with cGMP principles and guidelines. Compliance issues identified at our facilities or at third-party manufacturers may disrupt clinical or commercial production or distribution or require substantial resources to correct. This may result in the delay of clinical trials or commercial product launch. Discovery or problems with the product or the failure to comply with applicable requirements may result in restrictions on a product, the manufacturer or the holder of a marketing authorization, including withdrawal or recall of the product from the market or other EMA or EEA Competent Authority initiated action that could delay or prohibit future marketing.

Additionally, new government regulations may be established that could delay or prevent regulatory approval of our products under development.

United States Government Regulation

In the United States, section 351(i)(1) of the Public Health Service Act, or PHSA, defines a biological product (biologic) as a:

- "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, … applicable to the prevention, treatment, or cure of a disease or condition of human beings."

The information that must be submitted to the FDA in order to obtain approval to market a new biologic varies depending on whether the application for the biological product is submitted under section 351(a) or section 351(k) of the PHSA. Any proposed biologic, including a new product whose safety, purity and potency has not previously been demonstrated in humans, may follow the Biologics License Application, or BLA, route as defined by section 351(a). However, a proposed biologic whose active ingredient(s) and certain other properties are highly similar (biosimilar) to those of a previously approved biologic may follow an abbreviated licensure pathway as defined by section 351(k) of the PHSA. The FDA, under the authority of the Secretary of Health and Human Services, reviews and ultimately approves applications for biological products submitted under either pathway.

In addition, in the FDA's 2015 guidance document "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009," the FDA clarified that it intends to regulate any polymer composed of 40 or fewer amino acids, and any polymer made entirely by chemical synthesis and composed of fewer than 100 amino acids, as drugs under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, rather than as biologics under the PHSA, unless the polymer otherwise meets the statutory definition of a biological product. The process required by the FDA before a drug may be marketed in the United States generally involves the submission to the FDA of a New Drug Application, or NDA. The results of preclinical studies and clinical trials, along with information regarding the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA, and FDA review and approval of the NDA is necessary prior to any commercial marketing or sale of the drug in the United States. However, under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved branded product. Additionally, a pharmaceutical manufacturer may, under Section 505(b)(2) of the FFDCA, file an NDA that relies on studies not conducted by the applicant, or for which the applicant has not obtained a right of reference.

Drugs and biologics are also subject to other federal, state, and local statutes and regulation. If we fail to comply with applicable FDA or other requirements at any time during the drug development process, clinical testing, approval process or post-approval activities, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

BLA/NDA Approval Process

The process generally required by the FDA before a biologic or drug product candidate may be marketed in the United States involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current GLP regulations;

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety, purity and potency of the proposed biologic, and the safety and efficacy of the proposed drug for each indication;
- preparation of and submission to the FDA of a BLA or NDA after successful completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the biologic product in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical studies to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each clinical protocol and any subsequent protocol amendments must be submitted to the FDA as part of the IND, and an IRB at each site where the study is conducted must also approve the study. The IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries. Clinical trials typically are conducted in three or four sequential phases, but the phases may overlap or be combined.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.

- Phase 3. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product labeling and approval.
- Phase 4. In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the product. Such post-approval studies are typically referred to as Phase 4 clinical trials.

A pivotal trial is a clinical study that is designed to generate substantial evidence of product's safety and efficacy that adequately meets regulatory agency requirements to justify the approval of the product. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust.

Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Furthermore, the FDA, the IRB, or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee, and the sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once an NDA or BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. Similarly, the FDA reviews an NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's quality and purity.

Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities at which the product is manufactured. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA or NDA, the FDA will

typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, clinical data, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA is required to refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we and our partners may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a BLA or NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 trial or trials, and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical trials or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The FDA may also approve the BLA or NDA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates, and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our

contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- adverse publicity, fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant enforcement action and liability.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Patient Protection and Affordable Care Act, or PPACA, or Affordable Care Act, or ACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which amended the PHSA and created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing, and thereby lower development costs and increase patient access to affordable treatments. An application for licensure of a biosimilar product under section 351(k) of the PHSA must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

- analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- animal studies (including the assessment of toxicity); and
- a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) sufficient to demonstrate safety, purity and potency in one or more conditions for which the reference biologic product is licensed and intended to be used.

In addition, an application submitted under the 351(k) pathway must include information demonstrating that:

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;

- the condition or conditions of use prescribed, recommended, or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;
- the route of administration, the dosage form, and the strength of the proposed biosimilar product are the same as those for the reference product; and
- the facility in which the biological product is manufactured, processed, packed and held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Biosimilarity, as defined in PHSA §351(i), means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

In addition, section 351(k)(4) of the PHSA provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. To date, the FDA has not approved any biosimilar product as being interchangeable to the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- the proposed product is biosimilar to the reference product;
- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and
- for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the 351(k) approval pathway that are still being worked out by the FDA. For example, the FDA has discretion over the kind and amount of scientific evidence—laboratory, preclinical and/or clinical—required to demonstrate biosimilarity to a licensed biological product. According to FDA guidance:

> "the implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis."

The FDA intends to consider the totality of the evidence, provided by a sponsor to support a demonstration of biosimilarity, and recommends that sponsors use a stepwise approach in the development of their biosimilar products. Biosimilar product applications thus may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product. However, the FDA may refuse to approve a biosimilar application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The submission of an application via the 351(k) pathway does not guarantee that the FDA will accept the application for filing and review, as the FDA may refuse to accept applications that it finds are insufficiently complete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any

applicable user fees assessed under the Biosimilar User Fee Act of 2012 have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical studies and submit a BLA for licensure as a new biological product under section 351(a) of the PHSA.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application under the 351(k) pathway for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an "orphan drug") may be entitled to seven years of exclusivity under section 360cc of the FFDCA, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve-year period provided under §351(k) or the end of the seven-year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block §351(k) applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6).

Post Approval Requirements

After obtaining regulatory approval of a product, manufacturers may be required to comply with a number of post-approval requirements. For example, as a condition of approval of a BLA or a §351(k) application the FDA may require post marketing testing and surveillance to monitor the product's safety or efficacy.

In addition, the holder of an approved BLA or §351(k) application is required to timely report certain adverse reactions and production problems involving its product to the FDA to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for the product. Quality control and manufacturing procedures must also continue to conform to cGMPs after approval and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs.

Patent Disputes under the BPCIA

The BPCIA includes a detailed framework for addressing potential patent disputes between biosimilar product and reference product sponsors. Within 20 days after being notified that FDA has accepted its application for review, a 351(k) applicant must provide a copy of its application, along with any other information that describes the manufacturing processes for the biosimilar product, to the reference product sponsor's in-house counsel, the reference product sponsor's outside counsel, and/or a representative of the owner of a patent

exclusively licensed to the reference product sponsor with respect to the reference product who has retained a right to assert the patent or participate in litigation. The copy of the application and any other information provided are considered "confidential information" under the PHSA, and recipients are generally prohibited from disclosing anything contained therein and from using the information for any purposes other than to determine whether a patent infringement claim may reasonably be asserted. The reference product sponsor then has sixty days to provide the applicant with an initial list of patents that could reasonably be asserted. The reference product sponsor may also choose to designate patents that it would be willing to license to the applicant.

Within sixty days of receiving the initial list of patents from the reference product sponsor, the biosimilar applicant may provide the reference product sponsor with an initial list of patents that the applicant contends could reasonably be asserted by the reference product sponsor, and, for each patent on this list or the list provided by the reference product sponsor, must either (1) provide a claim-by-claim statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or will not be infringed, or (2) provide a statement that the applicant does not intend to begin marketing its product prior to the patent's expiration. The applicant must also respond to the reference product sponsor's list of patents available for licensing. If the applicant provided any statement regarding the non-infringement, invalidity, or unenforceability of any of the patents-at-issue, the reference product sponsor has sixty days to rebut such arguments and to provide the factual and legal basis for the reference product sponsor's option that the patent(s) will be infringed by the commercial marketing of the proposed biosimilar product.

Once the applicant has received the statement of the basis for the reference product sponsor's opinion, the parties have fifteen days to engage in good faith negotiations to agree on which if any of the patents will be the subject of an infringement action. The PHSA contemplates that the parties may not reach an agreement within this timeframe, in which case additional patent list exchange procedures are triggered. The applicant must first notify the reference product sponsor of the number of patents that it believes should be the subject of an infringement action. Subsequently, within five days of this notification and on a date agreed upon by the parties, the parties must simultaneously exchange lists of the patents that each believes should be the subject of an infringement action. The reference product sponsor may not list a greater number of patents than the number listed by the applicant, though if the applicant lists no patents the reference product sponsor may still list just one. Under this provision, the biosimilar applicant thus controls the number of patents that will be the subject of the infringement action.

Following this last list exchange, the reference product sponsor has thirty days to bring an infringement action for each patent on both lists. Alternatively, if the parties successfully negotiate an agreement regarding the patents that will form the basis for an infringement action, the reference product sponsor has thirty days after such agreement to bring an infringement action for each of the negotiated patents. Within thirty days of being served with a complaint in the infringement action, the applicant must provide notice to the FDA, and the FDA will publish notice of the complaint in the Federal Register. Unlike the Hatch-Waxman Act, under which a reference product sponsor must list its patents in the Orange Book, and the FDA will suspend its review for thirty months if a reference product sponsor files a patent infringement suit, the BPCIA does not direct the FDA to suspend review of the biosimilar product application as a result of the patent dispute.

For patents that are issued or licensed after the reference product sponsor has identified its initial list, the reference product sponsor may supplement its initial list with the additional patents within thirty days of the new patents' issuance or licensing. The biosimilar applicant must then respond within thirty days with a statement of the factual and legal basis for its opinion that the patent is invalid, unenforceable, or will not be infringed, or that the applicant does not intend to begin marketing its product prior to the patent's expiration. However, these patents do not become subject to the additional negotiation and list exchange procedures of the BPCIA, but rather are subject to preliminary injunction (PI) procedures. The BPCIA requires the biosimilar applicant to provide 180 day notice to the reference product sponsor of the applicant's intent to market the biosimilar product, and the reference product sponsor may then seek a PI on any patents there were included on any of the patent lists initially exchanged between the parties, but excluded from the patent list agreed to during negotiations or from

the lists that were exchanged as a result of the parties' failure to reach an agreement. Both parties must reasonably cooperate to expedite discovery as is needed in connection with the PI motion.

The BPCIA limits both the reference product sponsor and the biosimilar applicant from bringing actions for declaratory judgment (DJ). In particular, if the reference product sponsor has been provided confidential access to the biosimilar application, neither party may bring a DJ action before the reference product sponsor receives the applicant's 180 day advance notice of commercial marketing. Moreover, DJ actions may only be brought against patents for which a PI motion has been filed. Importantly, if the biosimilar applicant fails to respond to the reference product sponsor as required at the various steps of the BPCIA's patent dispute resolution framework, the reference product sponsor may bring a DJ action on any patent included on the reference product sponsor's initial list and its list of newly issued or licensed patents. If the applicant fails to provide access to the confidential information required to be provided at the start of the patent dispute process, the reference product sponsor may bring a DJ action on any patent that claims the biological product or its use.

The FDA has approved four applications submitted under the 351(k) pathway through December 31, 2016: Zarxio (filgrastim-sndz) on March 6, 2015, Inflectra (infliximab-dyyb) on April 5, 2016, Erelzi (etanercept-szzs) on August 30, 2016 and Amjevita (adalimumab-atto) on September 23, 2016. Thus, no typical review period for a biosimilar application has yet been established. However, the FDA aims to review 70%, 80%, 85%, and 90% of original (rather than resubmitted) biosimilar applications within ten months of receipt in fiscal years 2014, 2015, 2016, and 2017 respectively. The FDA did complete review of the Zarxio application within 10 months of a BLA filing (May 8, 2014). While it may be possible for a biosimilar applicant and reference product sponsor to settle any patent disputes prior to approval, patent litigation may delay the ability of a biosimilar applicant to sell commercial product in the United States, as was the case with Zarxio, which was launched in September 2015.

505(b)(2) New Drug Applications

The provisions of Section 505(b)(2) of the FFDCA were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant. Indeed, a new drug application filed under Section 505(b)(2) is one for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. We are pursuing a Section 505(b)(2) regulatory strategy for our PF708 product candidate and we plan to reference the Forteo (teriparatide) listed drug which is marketed by Eli Lilly for the treatment of osteoporosis.

The owner of an NDA for a branded drug product may list with the FDA certain patents whose claims allegedly cover the applicant's branded product. Each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files a 505(b)(2) new drug application referencing a drug listed in the Orange Book must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, referred to as a Paragraph I Certification; (2) such patent has expired, referred to as a Paragraph II Certification; (3) the date on which such patent expires, referred to as a Paragraph III Certification; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted, referred to as a Paragraph IV Certification. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. An applicant submitting a Paragraph IV Certification must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved branded drug to which the 505(b)(2) application refers. If the reference branded drug holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV Certification notice, the FDA is prohibited from approving the 505(b)(2) application until the earlier of 30 months from the receipt of the Paragraph IV Certification, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant.

Additionally, a 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the NDA branded reference drug has expired as described in further detail below. Market and data exclusivity provisions under the FFDCA can delay the submission or the approval of certain applications for competing products. In addition to patent exclusivity, the holder of the NDA for a reference listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve another drug application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any application for the same active moiety and that relies on the FDA's findings regarding that drug; the FDA may accept an application for filing after four years if the follow-on applicant makes a Paragraph IV Certification. A drug may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA that references such product until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the entire exclusivity period.

Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally half the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA or BLA.

The Animal Rule

In the case of product candidates that are intended to treat certain rare life-threatening diseases, such as our anthrax vaccine product candidates, conducting controlled clinical trials to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2015, often referred to as the "Animal Rule," the approval of such products can be based on clinical data from trials in healthy human subjects that demonstrate adequate safety and efficacy data from adequate and well-controlled animal studies. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, seeking approval under the Animal Rule may add significant time, complexity and uncertainty to the testing and approval process. In addition, products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of therapeutic equivalent products for branded prescription drugs. By way of example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, Affordable Care Act, contains provisions that may reduce the profitability of drug products, including, for example, increased the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care plans, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Furthermore, the current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on biosimilar manufacturers as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulations in the United States may have on our business.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we and our collaboration partners receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on cost containment measures in the United States and other countries has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we and our collaboration partners obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- The federal transparency laws, including the federal Physician Payment Sunshine Act, that requires drug manufacturers to disclose payments and other transfers of value provided to physicians and teaching hospitals and ownership and investment interests held by such physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, the Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the

Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, or FCA, (discussed below) or the civil monetary penalties statute.

We are also subject to the Foreign Corrupt Practices Act, or FCPA, which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid and imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Hazardous Materials

Our research and development processes may involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Competition

The development and commercialization of protein therapeutics is highly competitive. While we believe that our P*f*ēnex Expression Technology®, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, generic pharmaceutical, specialty pharmaceutical and biotechnology companies. In the event that we and our collaboration partners were to market and sell any of our biopharmaceutical products, we would face competition from the companies producing branded reference drugs, as well as any other firms developing the biosimilars that would compete with the product candidates in our pipeline and other novel products with similar indications. For example, PF582 may compete with products by Roche, as the reference product sponsor, Sandoz International GmbH, or Sandoz, a subsidiary of Novartis AG, Formycon AG, and bioeq GmbH as biosimilar companies and Ophthotech Corporation as a developer of novel products. Additionally, PF582 and Lucentis compete with globally marketed products including Eylea and Avastin (off label). Similarly, PF708, our teriparatide 505(b)(2) candidate, may face competition from the reference product sponsor, Eli Lilly, or other competition from companies like Teva and Gedeon Richter Plc., and from Amgen Inc. and Radius Health, Inc. as developers of novel products. Key competitive factors affecting the success of our lead product candidates, if approved, are likely to be price, the level of biosimilar, therapeutic equivalent and novel product competition and the availability of coverage and reimbursement from government and other third-party payors.

Similarly, our novel vaccine development programs face substantial competition from major pharmaceutical and other biotechnology companies that are actively working on improved and novel vaccines. We believe that our primary competitors include Emergent BioSolutions, Inc. and Altimmune, Inc. These companies are receiving funding from BARDA for the development of next generation anthrax vaccines. All of our novel vaccine efforts will face competition for limited government funding from other non-vaccine defensive measures as well, including medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures.

Further, many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and

development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective or more effectively marketed and sold than any treatment we may commercialize and may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to or necessary for our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Sales and Marketing

To date, none of our product candidates have completed clinical development, been submitted for regulatory review or received marketing authorization from any regulatory agency, and therefore we have not received revenue from the sale of any of our product candidates.

In light of our stage of development, we have not yet established commercial organization or distribution capabilities. Except for our agreements with Jazz and Strides Arcolab with respect to certain product candidates, we generally expect to retain commercial rights for our product candidates. In particular, we intend to use an internal sales force to commercialize products for which we may receive marketing approvals in territories in which we believe it is possible to access the market through a focused, specialty sales force.

Upon marketing approval, Jazz, our collaboration partner, will assume responsibility for the manufacturing and commercialization of certain hematology products globally. For products being developed as part of our joint venture with Strides Arcolab, we have joint responsibility for worldwide commercialization. Given the initial emerging markets focus for those products, we generally expect to jointly seek collaboration, distribution and/or marketing arrangements with third parties.

We have sales and marketing capabilities to support our commercial efforts for our protein production services and reagent protein product sales. In addition, we have sales and marketing capabilities to support those products under development that receive FDA approval that will ultimately be procured by the United States government.

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business, and seek to obtain and maintain patents for any patentable aspects of our platform technology and our products or product candidates, their methods of use and any other inventions that are important to the development of our business. Our success depends substantially on our ability to obtain and maintain patent and other proprietary protection for our technology and product candidates, to defend and enforce our patents to prevent others from infringing our proprietary rights, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology and product candidates that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position relating to our platform technology and product candidates.

We are the owner or licensee of a portfolio of patents and patent applications and possess substantial know-how and trade secrets which protect various aspects of our business. As of December 31, 2016, we were the sole owner of a patent portfolio that consisted of a total of 18 U.S. issued patents and six U.S. pending patent applications that provide material coverage for our platform technology and our lead product candidates as well as foreign granted and pending patent applications which are counterparts to certain of the foregoing U.S. patents and patent applications. Our U.S. issued patents expire during the time period beginning in 2025 and ending in 2033. Our owned and exclusively licensed patent portfolio includes claims directed to:

- methods for bacterial protein production and methods for rapid screening of an array of expression systems
- *P. fluorescens* promoter sequences and secretion leader sequences
- auxotrophic marker systems for antibiotic free maintenance of expression plasmids in high cell density cultures,
- improved incorporation of non-natural amino acids
- expression of classes of proteins such as cytokines
- antibody derivatives
- microbial toxins in *P. fluorescens*
- methods and expression strains for production and/or purification of soluble full length human cytokines, Interferon beta and G-CSF
- vaccine antigens recombinant anthrax protective antigen, microbial toxins and toxoids, and the malarial vaccine candidate antigen *P. falciparum* circumsporozoite protein (CSP)
- fusion partners for peptide production

Pursuant to the technology licensing agreement, The Dow Chemical Company, or TDCC, and Dow Global Technologies LLC, or DGTI, also grant to us non-exclusive licenses to U.S. patents and applications and their foreign counterparts covering methods and technologies for recovery of proteins and peptides from P. fluorescens cells. In conjunction with the licenses granted by TDCC and DGTI to us under the technology licensing agreement, we also entered into a grant-back and technology license agreement, pursuant to which we granted to TDCC exclusive and non-exclusive licenses under certain patent rights and know-how relating to our Pfēnex Expression Technology® to use certain biological materials to make, use and commercialize products in certain fields of use that do not include human therapeutics. See "Business—Collaborations, Joint Development and Licenses" for a detailed description of our agreements with TDCC and DGTI.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to obtain and maintain our proprietary position for our technology will depend on our success in obtaining issued claims that cover our technology and product candidates, and being able to enforce those claims against our competitors once granted. We do not know whether any of our pending patent applications will result in the issuance of any patents. Moreover, even our issued patents do not guarantee us the right to practice the patented technology in relation to the commercialization of our product candidates. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of the term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for both our biosimilar and vaccine products. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or

remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, advisors, contractors and collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see "*Risk Factors—Risks related to our intellectual property.*"

Environmental Matters

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including, small quantities of acetonitrile, methanol, ethanol, ethidium bromide and compressed gases, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We seek to comply with applicable laws regarding the handling and disposal of such materials. Given the small volume of such materials used or generated at our facilities, we do not expect our compliance efforts to have a material effect on our capital expenditures, earnings, and competitive position. However, we cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages, and suspension of our operations.

Suppliers

We currently rely on, and expect to continue to rely on, contract manufacturers to produce sufficient quantities of our product candidates for use in our clinical trials. In addition, we intend to rely on third parties to manufacture any products that we may commercialize in the future. We have established an internal pharmaceutical development group to develop manufacturing methods for our product candidates, to optimize manufacturing processes, and to select and transfer these manufacturing technologies to our suppliers. We contract with multiple manufacturers to ensure adequate product supply and to mitigate risk.

There currently are a limited number of these manufacturers. Furthermore, some of the contract manufacturers that we have identified to date only have limited experience at manufacturing, formulating, analyzing and packaging our product candidates in quantities sufficient for conducting clinical trials or for commercialization.

Manufacturing

We do not own or operate facilities for cGMP manufacturing of any products. Although we intend to rely on contract manufacturers, we have personnel with experience in the development of United States and European Union cGMP-compliant processes and management of Contract Manufacturing Organizations ("CMOs"), to oversee the technology transfer to the manufacturers of PF708, PF582, Px563L, Px533 and future product

candidates that we may develop. Our manufacturing processes employ standard equipment common to CMOs. Our processes also use common and widely available materials, and our well-established manufacturing procedures are robust, scalable, and readily transferable to support our clinical development programs and commercialization of our products. We believe that there are alternate sources of supply that can satisfy our clinical and commercial requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs. For a discussion of risks related to our sources and availability of supplies, see *"Risk Factors—Risks Relating to our Reliance on Third Parties – We rely on third-party suppliers, and in some instances a single third-party supplier, for the manufacture and supply of certain materials in our protein production services, and these suppliers could cease to manufacture the materials, go out of business or otherwise not perform as anticipated."*

In each of our agreements with contract manufacturers, we retain ownership of our intellectual property and generally own and/or are assigned ownership of processes, developments, data, results and other intellectual property generated during the course of the performance of each agreement that primarily relate to our products. Where applicable, we are granted non-exclusive licenses to certain contract manufacturer intellectual property for purposes of exploiting the products that are the subject of the agreement, and in a few instances we grant non-exclusive licenses to the contract manufacturers for use outside of our product area. In each contract, we have the right to terminate for convenience. The agreements also contain typical provisions for both parties to terminate for material breach, and bankruptcy and insolvency.

PF582. In December 2016, we entered into a contract manufacturing agreement for the cGMP manufacturing of PF582.

Px563L. In July 2015, we entered into a contract manufacturing agreement for the cGMP fill and finish of Px563L drug product for use in the Phase 1a clinical trial that was initiated in December 2015. All manufacturing costs are funded by BARDA, pursuant to the contract awarded to us in August 2015.

Protein Production

Utilizing our P*f*ēnex Expression Technology®, we provide protein production and process development services to third parties on a fee for service basis in support of the development of novel biopharmaceuticals. Pursuant to a license agreement, the third-party licenses a production strain from us and then pays us an up-front payment, milestone payments based upon clinical progression and regulatory filings, and a royalty based on product net sales. Our protein production efforts enable us to maximize the utilization of our P*f*ēnex Expression Technology®, expand our institutional knowledge and generate revenue.

Seasonality

Our revenues are not seasonal in nature.

U.S. Government Contracts

Revenue from U.S. Government contracts varies by year. A portion of our government business is subject to renegotiation of profits or termination of contracts or subcontracts at the election of the U.S. Government. In addition to contract terms, we must comply with procurement laws and regulations relating to the formation, administration, and performance of U.S. Government contracts. Failure to comply with these laws and regulations could lead to the termination of contracts at the election of the government or the suspension or debarment from U.S. Government contracting or subcontracting. U.S. Government revenue as a percentage of our total revenue was approximately 10%, 48% and 74% for fiscal years 2016, 2015 and 2014, respectively. For further discussion of risks related to government contracting, see the discussion in Item 1A, "*Risk Factors*" in this Form 10-K.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2016, we had 63 employees, including a total of 16 employees who hold M.D. and/or Ph.D. degrees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

Backlog

We have no material backlog of orders.

Research and Development

Over the last three fiscal years, we have invested over $54.7 million in principal research and development programs ($32.4 million, $18.2 million and $4.1 million for the years ended December 31, 2016, 2015 and 2014, respectively). Please see "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in this Annual Report on Form 10-K for additional information related to research and development expenditures.

Geographic Information

During 2016, substantially all of our long-lived assets were located within the United States. With the exception of $0.1 million of long-lived assets held by a third-party vendor in India for manufacturing purposes, during 2015 all of our long-lived assets were located within the United States. During 2014, all of our long-lived assets were located within the United States. Approximately 9% of our revenue for 2016, 12% of our 2015 revenue, and 18% of our 2014 revenue came from international markets. Please see *Note 1* to our audited financial statements included in Item 8 of this Annual Report on Form 10-K for additional information related to our U.S. and non-U.S. revenue.

Corporate Information

We were founded in November 2009 as a Delaware corporation spun out of The Dow Chemical Company. Our principal executive offices are located at 10790 Roselle St., San Diego, California 92121 and our telephone number is (858) 352-4400. Our website is www.pfenex.com. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. Our SEC reports can be accessed through the investor relations page of our website located at http://pfenex.investorroom.com. Additionally, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on our investor relations page of our website. Corporate governance information, including our board committee charters, code of ethics and conduct, and corporate governance principles, is also available on our investor relations page of our website located at http://pfenex.investorroom.com/corporate-governance. In addition, we use our website (http://www.pfenex.com), our investor relations website (http://pfenex.investorroom.com), press releases, SEC filings, public conference calls, corporate Twitter account (https://twitter.com/pfenex), Facebook page (https://www.facebook.com/Pfenex-Inc-105908276167776/timeline), and LinkedIn page (https://www.linkedin.com/company/pfenex-inc) in order to achieve broad, non-exclusionary distribution of information to the public. We encourage our investors and others to review the information we make public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

The contents of our website and the information we post through social media are not a part of, and are not incorporated by reference into, this Annual Report on Form 10-K or any other report or document we file with the SEC, and any references to our website and social media sites are intended to be inactive textual references only.

Pfenex™, the Pfenex logo and other trademarks or service marks of Pfenex appearing in this Annual Report on Form 10-K are the property of Pfenex Inc. Trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 10-K are the property of their respective holders.

Executive Officers

The following table identifies certain information about our executive officers as of March 2, 2017.

Name	Age	Position
Patrick K. Lucy	49	Interim Chief Executive Officer, President, and Secretary, and Chief Business Officer
Paul A. Wagner	46	Chief Financial Officer
Patricia Lady	58	Chief Accounting Officer
Hubert C. Chen	48	Chief Medical Officer
Henry W. Talbot	65	Vice President, Operations
Steven S. Sandoval	51	Chief Manufacturing Officer

Patrick K. Lucy is currently serving as our Interim Chief Executive Officer, President, and Secretary, and Chief Business Officer. He has served as our Chief Business Officer since 2014 and our Vice President of Business Development and Marketing between 2009 and 2014. Prior to joining us, Mr. Lucy held the position of Director of Business Development at DowPharma, a business within The Dow Chemical Company, a chemicals manufacturer, from 2002 to 2009. From 1999 to 2002, he held the position of Director of Business Development at Collaborative BioAlliance, Inc., a biotechnology company, which was acquired by The Dow Chemical Company. From 1998 to 1999, Mr. Lucy worked as a Validation Manager and Capital Project Manager and from 1996 to 1998, as a Quality Control Biochemistry Supervisor at Lonza Biologics Inc., a chemicals and biotechnology company. From 1991 to 1996, Mr. Lucy held various positions at Repligen Corporation, a life sciences company. Mr. Lucy holds a Bachelor's degree in Biology from Villanova University.

Paul A. Wagner has served as our Chief Financial Officer since 2014. From 2006 to 2014, Dr. Wagner held the positions of Director and Portfolio Manager/Sr. Equity Analyst with Allianz Global Investors, a diversified active investment manager where he was responsible for biotechnology and pharmaceutical investments. Prior to that, Dr. Wagner was the Head of Development Licensing at PDL BioPharma, a diversified biopharmaceutical company from 2005 until 2006. Prior to PDL BioPharma, Dr. Wagner held the position of Vice President at Lehman Brothers, a global financial services firm, starting in 1999 until 2005. Dr. Wagner received a B.S. from the University of Wisconsin and a Ph.D. in Chemistry from the California Institute of Technology. Dr. Wagner is also a CFA charterholder.

Patricia Lady has served as our Chief Accounting Officer since 2011. Prior to serving in her current role, Ms. Lady served as our Director of Finance and Corporate Controller from 2009 to 2011. From 2007 to 2009, she served as Director of Finance and Accounting at Neurocrine Biosciences, Inc., a biopharmaceutical company. From 2006 to 2007, Ms. Lady held the position of Corporate Controller of Avanir Pharmaceuticals, Inc., a pharmaceutical company. From 2001 to 2005, Ms. Lady held the position of Vice President of Finance at 3E Company, a technology company. From 2000 to 2001, she served as Vice President of Business Development of Everypath, Inc., a technology company. From 1999 to 2000, Ms. Lady held the position of Vice President of Business Development and Marketing at iOwn, Inc., a technology company. From 1997 to 1999, she served as Vice President of Business Development at Careerbuilder, a technology company. Ms. Lady is a certified public

accountant, a chartered global management accountant and a certified management accountant. Ms. Lady holds a Bachelor's degree in Accounting from California State University, Fullerton and an M.B.A. from the University of California, Los Angeles.

Hubert C. Chen has served as our Chief Medical Officer since November 2014. From July 2012 to October 2014, Dr. Chen served as Vice President, Clinical Development of Aileron Therapeutics, a biopharmaceutical company developing and advancing drugs using novel peptide-stabilizing technologies. From September 2009 to June 2012, Dr. Chen served as Vice President, Translational Medicine of Regulus Therapeutics, a biopharmaceutical company focused on the discovery and development of microRNA therapeutics. From September 2006 to September 2009, Dr. Chen served as Director, Clinical Research and Senior Director, Clinical Research and Corporate Development of Amylin Pharmaceuticals, a biopharmaceutical company engaged in the discovery, development and commercialization of drug candidates for the treatment of diabetes, obesity and other diseases. From March 2004 to September 2006, Dr. Chen served as Associate Director, Medical Sciences of Amgen, Inc., a biopharmaceutical company discovering, developing, and manufacturing of innovative human therapeutics. Additionally, from 2002 to 2012, Dr. Chen served as Assistant Clinical Professor of Medicine and Clinical Instructor of Medicine at the University of California, San Francisco. From 2001 to 2004, Dr. Chen served as a Staff Research Investigator, Staff Scientist, and Research Scientist at the Gladstone Institute of Cardiovascular Disease. Dr. Chen received his medical residency training at Massachusetts General Hospital from 1995 to 1998, his M.D. from Columbia University in 1995 and his B.A.S. in political science and biological sciences from Stanford University in 1991.

Henry W. Talbot has served as our Vice President of Research and Operations since 2009. Prior to joining us, Dr. Talbot held the position of Biotechnology Site Leader at The Dow Chemical Company, a chemicals manufacturer, from 1999 to 2009. From 1994 to 1998, Dr. Talbot was Director of Fermentation and Manufacturing at Mycogen Corporation, an agricultural sciences company, prior to it being acquired by The Dow Chemical Company in 1998. Dr. Talbot holds a Bachelor's degree in Biology from the University of Colorado, Boulder, a Master of Science degree in Microbiology from the University of Missouri and a Ph.D. in Microbiology from Oregon State University.

Steven S. Sandoval Sr. has served as our Chief Manufacturing Officer since September 2016. Prior to joining us, Mr. Sandoval founded and served as the President and Chief Executive Officer of Pharmaceutical Technical Solutions, Inc., a technical consulting firm, from 2010 to September 2016. From 2015 to 2016, Mr. Sandoval held the position of Vice President, Engineering/Facilities of BioSciencesCorp LLC, a pharmaceutical consulting company. Prior to that, Mr. Sandoval held various senior management positions with Maple Leaf Foods Inc., a consumer foods firm, including Commissioning Director from 2010 to 2014 and Engineering Director from 2014 to 2015. From 2008 to 2009, Mr. Sandoval served as Lead Senior Construction Manager for Parsons, Inc., an engineering and construction firm. From 1989 to 2008, Mr. Sandoval held various management positions at Amgen, Inc., a biopharmaceutical company, including Facilities and Engineering Director from 2004 to 2008.

Item 1A. ***Risk Factors***

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Relating to our Financial Condition and Need for Additional Capital

We have a limited operating history and expect to generate significant losses for the foreseeable future. If we do not generate significant revenue, we will not be profitable.

With the exception of two years, we have incurred annual net operating losses since inception, and to date have generated only limited revenue from government contracts, service agreements, collaboration agreements, and reagent protein product sales. We have recognized net income of $5.5 million for the year ending December 31, 2016 and net losses of $28.2 million and $9.8 million for the years ending December 31, 2015 and 2014, respectively, and had an accumulated deficit of $136.0 million and net working capital of $69.7 million as of December 31, 2016. To date, we have funded our operations primarily through the sale and issuance of common stock in our public offerings, revenue from our collaboration agreements, government contracts, service agreements, and reagent protein product sales, our prior credit facility and the private placement of equity securities. As a result of the termination of the development and license agreement with Pfizer in August of 2016, we will need to invest or find a collaboration partner to invest significant resources in the further development of PF582. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred. As of December 31, 2016, we had capital resources consisting of cash and cash equivalents of $81.5 million.

As we continue to develop and invest more resources into the development and commercialization of our product candidates, we expect that our expenses will increase substantially, and that our net operating losses will increase over the next several years. To become profitable, we must successfully develop and obtain regulatory approval for our product candidates, and effectively manufacture and commercialize the product candidates we develop. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our and our collaboration partners' ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. We may never succeed in these activities and therefore may never generate revenue that is significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We will require substantial additional funds to seek and obtain regulatory approval for and commercialize our two most advanced biosimilar and therapeutic equivalent product candidates and our other product candidates and, if additional capital is not available, we may need to limit, scale back or cease our operations.

Since our inception, a significant portion of our resources have been dedicated to the preclinical and clinical development of our two most advanced biosimilar and therapeutic equivalent product candidates, PF708 and PF582. We believe that we will continue to expend substantial resources for the foreseeable future for the preclinical and clinical development of our current product pipeline, and the development of any other indications and product candidates we may choose to pursue, either alone or with our strategic collaboration partners. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply as well as marketing and selling any products approved

for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of PF708, PF582 and our pipeline of other product candidates and preclinical products under development. As a result of the termination of the development and license agreement with Pfizer, management is assessing all opportunities for the continued advancement of PF582, and we may be required to devote additional resources to the development of PF582 or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us. We may also need to obtain substantial additional sources of funding to develop PF582 as currently contemplated. If such additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our PF582 development program, or grant rights in the United States, as well as outside the United States, to PF582 to one or more partners.

We believe that our available cash and cash equivalents, including the proceeds from any revenue from our government contracts, service agreements, collaboration agreements, and reagent protein product sales will allow us to fund our operations for at least the next 12 months. In addition, we may seek additional capital due to favorable market conditions or strategic considerations; even if we believe we have sufficient funds for our current or future operating plans. Our future capital requirements may vary depending on the following:

- the timing and extent of spending on our research and development efforts, including with respect to PF708, PF582 and our other product candidates;
- our ability to enter into and maintain collaboration, licensing, commercialization and other arrangements and the terms and timing of such arrangements;
- the cost of manufacturing and commercialization activities, if any;
- the receipt of any collaboration or milestone payments;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the emergence of competing technologies or other adverse market developments;
- the time and costs involved in seeking and obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- if approved, the degree and rate of market acceptance of any products launched by us or our collaboration partners;
- the expansion of our sales and marketing activities; and
- the potential acquisition and in-licensing of other technologies, products or assets.

If we were to experience any delays or encounter issues with any of the above, including clinical holds, failed studies, inconclusive or hard-to-interpret results, safety or efficacy issues, or other regulatory challenges that require longer follow-up of existing studies, additional major studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above and delay revenues.

We will need to raise additional capital to fund our operations in the near future. If we seek additional funding in the future, additional funds may not be available to us on acceptable terms or at all. We may seek to

raise additional funds through equity, equity-linked or debt financings. If we raise additional funds through the incurrence of indebtedness, such indebtedness would have rights that are senior to holders of our equity securities and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail the advancement of one or more of our product candidates. We also could be required to seek funds through arrangements with collaboration partners or others that may require us to relinquish rights to some of our technologies or product candidates which we would otherwise pursue on our own.

The termination of our development and license agreement with Pfizer resulted in all rights to PF582 being returned to us. Any further development of PF582 will require significant resources from us or another collaboration partner, and in the event that we do not find a collaboration partner, the development of PF582 could be significantly delayed or result in the discontinuation of the development of PF582.

In August 2016, we and Pfizer entered into a termination agreement pursuant to which our development and license agreement was terminated and all rights to PF582 were returned to us. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred and we will not recognize any additional future revenue under the Pfizer license agreement.

Additionally, further development of PF582 will require significant resources from us or another collaboration partner. We or a new collaboration partner will be responsible for funding any new PF582 development and clinical trial activities undertaken after the termination. Any such further development will require significant resources to develop and commercialize PF582, and such further development may not be possible in the near term without a new collaboration partner**.** There are no assurances that we will have access to additional capital or find a new collaboration partner or that the terms and timing of any such arrangements would be acceptable to us. As a result, we could experience a significant delay in the PF582 development process. If we determine instead to discontinue the development of PF582, we will not receive any future return on our investment from that product candidate.

Our quarterly operating results may fluctuate significantly.

Our operating results are subject to quarterly fluctuations. Our operating results are affected by numerous factors, including:

- variations in the level of expenses related to our PF708 and PF582 development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting any of our products; and
- our execution of any service, collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the market price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the market price of our stock to fluctuate substantially.

Risks Relating to our Business and our Industry

If an improved version of a reference product, such as Lucentis or Forteo, is developed, or if the market for a reference product significantly declines, sales or potential sales of our biosimilar and therapeutic equivalent product candidates may suffer.

Reference product sponsor companies may develop improved versions of a reference product as part of a life cycle extension strategy, and may obtain regulatory approval of the improved version under a supplemental

biologics license application. If a reference product sponsor company succeeds in obtaining an approval of an improved product, it may capture a significant share of the collective reference product market and significantly reduce the market for the reference product, and thereby the potential size of the market for our biosimilar and therapeutic equivalent product candidates. In addition, the improved product may be protected by additional patent rights.

Additionally, competition in the pharmaceutical market is intense. Reference products face competition on numerous fronts as technological advances are made that may offer patients a more convenient form of administration or increased efficacy, or as new products are introduced. As new products are approved that compete with the reference product to our biosimilar and therapeutic equivalent product candidates, such as Lucentis or Forteo, sales of the reference products may be significantly and adversely impacted and may render the reference product obsolete. If the market for the reference product is impacted, we in turn may lose significant market share or market potential for our products and product candidates. As a result, the value of our product pipeline could be negatively impacted and our business, prospects and financial condition could suffer.

Our product candidates, if approved, will face significant competition from the reference products and from other biosimilars and therapeutic equivalent products of the reference products. Our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical market have the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to consumers and medical professionals. Numerous companies, universities, and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors, such as Novartis AG, Genentech, Inc., a wholly-owned member of the Roche Group, Amgen Inc. and Eli Lilly and Company, are large, experienced companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. Recent and potential future merger and acquisition activity in the biotechnology and pharmaceutical industries are likely to result in even more resources being concentrated among a smaller number of our competitors. These companies also maintain greater brand recognition and more experience and expertise in undertaking preclinical testing and clinical trials of product candidates, and obtaining the U.S. Food and Drug Administration, or FDA, and other regulatory approvals of products. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds that could make our product candidates obsolete.

In addition, our biosimilar and therapeutic equivalent products may face competition from companies that develop and commercialize biosimilars and therapeutic equivalent products that compete directly with our products. See *"Risks Related to Government Regulation — If other biosimilars of Lucentis or other therapeutic equivalent products to Forteo are approved and successfully commercialized before PF708 or PF582, our business would suffer."*

Use of our product candidates could be associated with side effects or adverse events.

Use of our product candidates could be associated with side effects or adverse events which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized, and any such side effects or adverse events may negatively affect our and our collaboration partners' ability to obtain and maintain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. We may be required by regulatory agencies

to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. We may also be required to change our product labeling, including increasing the prominence and content of warnings and contraindications for our products. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

In addition, if we and our collaboration partners are successful in commercializing PF708 and PF582 or any other product candidates the FDA, European Medicines Agency, or EMA, European Economic Area Competent Authorities, or EEA Competent Authorities, and other foreign regulatory agency regulations require that we timely report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We or our collaboration partners may fail to report adverse events we become aware of within the prescribed timeframe. We or our collaboration partners may also fail to appreciate that we or our collaboration partners have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we or our collaboration partners fail to comply with our reporting obligations, the FDA, the EMA, EEA Competent Authorities, or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop PF708, PF582 or any future product candidates, conduct our clinical trials and commercialize PF708, PF582 or any future product candidates we develop.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly our Interim Chief Executive Officer and Chief Business Officer, Chief Financial Officer, and Chief Medical Officer, as well as our senior scientists and other members of our senior management team. Employment agreements with each of our Chief Executive Officer and Chief Business Officer, Chief Financial Officer, Chief Medical Officer, and other senior executives, as well as our offer letters with our senior scientists, all provide for "at-will" employment. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of PF708, PF582 or any future products we develop.

We are currently undertaking a search for a permanent chief executive officer. The transition to a permanent chief executive officer may be disruptive to our business and, during the transition period, there may be uncertainty among investors and others concerning our future direction and performance. It also may be more difficult for us to recruit and retain other personnel until a permanent chief executive officer is identified. The failure to successfully hire a chief executive officer or other executives and key employees, or the loss of any additional executives and key employees, could have a significant impact on our operations.

Although we have not historically experienced significant difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

We currently rely on a limited number of collaboration partners for a substantial portion of our revenue. The loss of or a change in any significant collaboration partner, including its credit worthiness, could materially reduce our revenue and adversely impact our financial position.

One collaboration partner accounted for more than 10% of our 2016 revenue, two collaboration partners accounted for more than 10% of our 2015 revenue, and three collaboration partners accounted for more than 10%

of our revenue in 2014. Pfizer accounted for more than 10% of our 2016 revenue, and Pfizer and the Biomedical Advanced Research and Development Authority, or BARDA, each accounted for more than 10% of our revenue in 2015. BARDA, the National Institute of Allergy and Infectious Diseases, or NIAID, and Boehringer Ingelheim International GmbH each accounted for more than 10% of our revenue in 2014.

In August 2016, we entered into a termination agreement with Pfizer pursuant to which our development and license agreement was terminated and all rights to PF582 returned to us. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred and we will not recognize any additional future revenue under this agreement. Pfizer will no longer be responsible for manufacturing, clinical studies and commercialization of PF582. We will not receive additional revenue from Pfizer.

The loss of any key collaboration partner or any significant adverse change in the size or terms of a contract with a key collaboration partner, such as the termination of the development and license agreement with Pfizer in August 2016, could significantly reduce our revenue over the short term. Moreover, having our revenue concentrated among a limited number of entities creates a concentration of financial risk for us, and in the event that any significant collaboration partner is unable to fulfill its payment obligations to us, our operating results and cash position would suffer. See *"Risks Relating to our Reliance on Third Parties — We are substantially dependent on the expertise of Strides Arcolab and Jazz to develop and commercialize some of our product candidates. If we fail to maintain our current strategic relationship with Strides Arcolab and Jazz, our business, commercialization prospects and financial condition may be materially adversely affected.*"

We currently have limited marketing capabilities and no sales organization.

We currently have limited sales and marketing capabilities. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team.

We will need to invest or find a collaboration partner to invest significant resources in the further development of PF582. In the event that we independently advance PF582 as a wholly-owned product candidate, we will need to identify potential sales, marketing and distribution partners or establish our own internal sales force. For PF708, we will need to identify potential sales, marketing and distribution partners or establish our own internal sales force. In the future, we may choose to collaborate with other third parties that have direct sales forces and established distribution systems, either to augment our own sales force or in lieu of our own sales force. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

We enter into various contracts in the normal course of our business that periodically incorporate provisions whereby we indemnify the other party to the contract. In the event we would have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial position and results of operations.

In the normal course of business, we periodically enter into academic, commercial and consulting agreements that contain indemnification provisions. With respect to our academic agreements, we may be required to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to commercial agreements entered into with our protein production customers, we typically provide indemnification for claims from third parties arising out of any potential intellectual property infringement

associated with our P*f*ēnex Expression Technology® in the course of performing our services. With respect to our commercial agreements, the bulk of which are with contract manufacturers, we indemnify our vendors from third-party product liability claims which result from the production, use or consumption of the product, as well as for certain alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services. In all of the above cases, we do not indemnify the parties for claims resulting from the negligence or willful misconduct of the indemnified party.

In certain circumstances, we maintain insurance coverage which we believe may limit our obligations under certain of these indemnification provisions. However, we do not carry insurance for all risks that our business may encounter, including our obligations under certain indemnification provisions. To the extent we do not have insurance to cover certain indemnification obligations, we are denied insurance coverage, or our obligation under an indemnification provision exceeds applicable insurance coverage, any significant, uninsured liability may require us to pay substantial amounts, which would adversely affect our working capital and results of operations.

We may have difficulty managing our growth and expanding our operations successfully.

As we advance our product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other organizations.

As of December 31, 2016, we had 63 full-time employees. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Therefore, we will need to continue to expand our managerial, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. In order to effectively execute our growth strategy, we will be required to:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- establish and maintain collaborations with third parties for the development and commercialization of our product candidates, or otherwise build and maintain a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, this expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue, and operating results.

The U.S. government holds certain intellectual property rights related to our Anthrax vaccine, Px563L and Malaria vaccine, Px533.

Although we have intellectual property related to expression of recombinant protective antigen in *P. fluorescens*, the U.S. government holds certain patents related to the recombinant protective antigen, as well as certain license rights to intellectual property related to other Px563L components used to produce the final

vaccine, which, if exercised, could materially impact our business, revenue and operating results. We have rights to utilize this intellectual property held by the U.S. government by virtue of the Authorization and Consent clauses of our contracts with the U.S. government.

Our contracts with the U.S. government, and our subcontracts with U.S. government contractors, require ongoing funding decisions by the U.S. government; reduced or discontinued funding of these contracts could cause our financial condition and operating results to suffer materially.

Development of our anthrax vaccine, Px563L, is funded by BARDA and development of our Px563L-SDI anthrax vaccine and our malaria vaccine, Px533, is funded by NIAID. The funding for government programs is subject to Congressional appropriations, often made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. Additionally, our government-funded development contracts give the U.S. government the right, exercisable in its sole discretion, to extend this contract for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under its contracts with us, our business, revenue and operating results would suffer.

Our current contracts with BARDA and NIAID are cost plus fixed fee contracts and potential future contracts with the U.S. government may also be structured this way. Under our cost plus fixed fee contracts, we are allowed to recover our approved costs plus a fixed fee. The total price on a cost plus fixed fee contract is based primarily on allowable costs incurred, but generally is subject to contract funding limitations. U.S. government regulations require us to notify our customer of any cost overruns or underruns on a cost plus contract. If we incur costs in excess of the funding limitation specified in the contract, we may not be able to recover those cost overruns.

Moreover, changes in U.S. government contracting policies could directly affect our financial performance. Factors that could materially adversely affect our U.S. government contracting business include:

- budgetary constraints affecting U.S. government spending generally, or specific departments or agencies in particular;
- changes in U.S. government fiscal policies or available funding;
- changes in U.S. government defense and homeland security priorities;
- changes in U.S. government programs or requirements;
- adoption of new laws or regulations;
- technological developments;
- U.S. government shutdowns, threatened shutdowns or budget delays;
- competition and consolidation in our industry; and
- general economic conditions.

These or other factors could cause U.S. government departments or agencies to reduce their development funding or future purchases under contracts, to exercise their right to terminate contracts or fail to exercise their options to extend our contracts, any of which could have a material adverse effect on our business, financial condition, operating results and ability to meet our financial obligations.

Unfavorable provisions in government contracts, some of which are customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our financial condition and operating results.

Government contracts contain provisions that give the U.S. government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the U.S. government to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify the government's obligations under such contracts or subcontracts, without the contractor's consent, including by imposing equitable price adjustments;
- audit contract-related costs and fees, including allocated indirect costs;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- under certain circumstances involving public health and safety, license inventions made under such agreements to third parties;
- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts;
- suspend or debar the contractor from doing future business with the government;
- decline to exercise an option to continue a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;
- change the course of a development program in a manner that differs from the contract's original terms or from our desired development plan, including decisions regarding our partners in the program;
- pursue civil or criminal remedies under the False Claims Act, or FCA, and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our contracts with BARDA and NIAID, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;

- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program;
- mandatory internal control systems and policies; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential contract or FCA liability and to termination of our contracts.

Furthermore, we are required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors in order to satisfy our contractual obligations pursuant to our agreements with the United States government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our government contract. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our contract.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

Most U.S. government contracts grant the U.S. government the right to use on a royalty free basis, for or on behalf of the U.S. government, any technologies developed and data first produced by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the U.S. government.

Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.

U.S. government agencies such as the Department of Health and Human Services, or HHS, and the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors and recipients of federal grants and contracts. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The HHS and the DCAA also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's accounting, purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;

- fines; and
- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

The United States government's determination to award a future contract may be challenged by an interested party, such as another bidder, at the United States Government Accountability Office, or the GAO, or in federal court. If such a challenge is successful, any future contract we may be awarded may be terminated.

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and interested parties may challenge the award of a government contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate the contract and resolicit proposals. The government agencies with which we have contracts could even be directed to award a potential contract to one of the other bidders.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our government contracts, including our contracts with BARDA and NIAID. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the Truth in Negotiations Act, which requires certification and disclosure of cost or pricing data in connection with contract negotiations;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and include other requirements such as the Anti-Kickback Statute and Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Any material changes in applicable laws and regulations could restrict our ability to maintain our existing BARDA and NIAID contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations.

Agreements with government agencies may lead to claims against us under the Federal False Claims Act, and these claims could result in substantial fines and other penalties.

The biopharmaceutical industry is, and in recent years has been, under heightened scrutiny as the subject of government investigations and enforcement actions. Our government contracts are subject to substantial financial

penalties under the Federal Civil Monetary Penalties Act and the FCA. Under the FCA's "whistleblower" provisions, private enforcement of fraud claims against businesses on behalf of the U.S. government has increased due in part to amendments to the FCA that encourage private individuals to sue on behalf of the government. These whistleblower suits, known as qui tam actions, may be filed by private individuals, including present and former employees. The FCA statute provides for treble damages and up to $11,000 per false claim. If our operations are found to be in violation of any of these laws, or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any future products we develop.

We face a risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may incur liability if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for PF708, PF582 or any future product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could impact the commercialization of PF708, PF582 and any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing PF708, PF582 or any other product candidates, we intend to expand our insurance coverage to include the sale of such products; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

Our employees, independent contractors, principal investigators, CROs, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, third-party clinical research organizations, or CROs, consultants and collaboration partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) regulations of the FDA and comparable foreign authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics and Conduct, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our cash and cash equivalents and short term investments could be adversely affected if the financial institutions in which we hold our cash and cash equivalents and short term investments fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance limit. While we monitor the cash balances in our accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

We may be subject to information technology failures, including data protection breaches and cyber-attacks, that could disrupt our operations, damage our reputation and adversely affect our business, operations, and financial results.

We rely on our information technology systems for the effective operation of our business and for the secure maintenance and storage of confidential data relating to our business and third party businesses. Although we have implemented security controls to protect our information technology systems, experienced programmers or hackers may be able to penetrate our security controls, and develop and deploy viruses, worms and other malicious software programs that compromise our confidential information or that of third parties and cause a disruption or failure of our information technology systems. Any such compromise of our information technology systems could result in the unauthorized publication of our confidential business or proprietary information, result in the unauthorized release of customer, supplier or employee data, result in a violation of privacy or other laws, expose us to a risk of litigation, or damage our reputation. The cost and operational consequences of implementing further data protection measures either as a response to specific breaches or as a

result of evolving risks, could be significant. In addition, our inability to use or access our information systems at critical points in time could adversely affect the timely and efficient operation of our business. Any delayed sales, significant costs or lost customers resulting from these technology failures could adversely affect our business, operations and financial results.

Third parties with which we conduct business have access to certain portions of our sensitive data. In the event that these third parties do not properly safeguard our data that they hold, security breaches could result and negatively impact our business, operations and financial results.

Our business involves the use of hazardous materials and we, our collaboration partners, and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including small quantities of acetonitrile, methanol, ethanol, ethidium bromide and compressed gases, and other hazardous compounds. We and our collaboration partners, manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations.

We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, and the handling of biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. For claims not covered by workers' compensation insurance, we also maintain an employer's liability insurance policy in the amount of $1.0 million per occurrence and in the aggregate. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

Environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Any inability to comply with environmental laws and regulations may adversely affect our business and operating results.

Changes in accounting principles, or interpretations thereof, could have a significant impact on our financial position and results of operations.

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, referred to as GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles. A change in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Additionally, the adoption of new or revised accounting principles may require that we make significant changes to our systems, processes and controls.

It is not clear if or when these potential changes in accounting principles may become effective, whether we have the proper systems and controls in place to accommodate such changes and the impact that any such changes may have on our financial position and results of operations.

Risks Relating to our Reliance on Third Parties

We are substantially dependent on the expertise of Strides Arcolab and Jazz to develop and commercialize some of our product candidates. If we fail to maintain our current strategic relationship with Strides Arcolab and Jazz, our business, commercialization prospects and financial condition may be materially adversely affected.

Because we have limited or no capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we may need to enter into alliances with other companies to develop our product candidates. For example, we have entered into agreements with Strides Arcolab and Jazz, pursuant to which we will transfer the development, manufacture and commercialization of some of our products.

In February 2015, we entered into a development and license agreement with Pfizer to develop and commercialize PF582. In August 2016, we entered into a termination agreement with Pfizer pursuant to which the development and license agreement was terminated and all rights to PF582 have been returned to us. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred and we will not recognize any additional future revenue under the Pfizer development and license agreement. We may seek a new collaboration partner for the development and commercialization of PF582, however there are no assurances that we can find a new collaboration partner or that the terms and timing of any such arrangements would be acceptable to us. As a result, we could experience a significant delay in the PF582 development process.

For the products included in the Joint Development & License Agreement, or JDLA, Strides Arcolab is responsible for development expenses up to Phase 3, at which time we will share in expenses and revenue going forward. Additionally, we will transfer the development, manufacture and commercialization of the products to a joint venture company jointly owned by us and Strides Arcolab upon completion of Phase 1 trials.

In July 2016, we entered into a license and option agreement with Jazz, pursuant to which we and Jazz will collaboratively develop certain hematology products, and Jazz will have the exclusive right to manufacture and commercialize such products throughout the world. In addition, pursuant to the agreement, we have granted Jazz certain other rights to negotiate the exclusive right to develop, manufacture and commercialize throughout the world other hematology products that are currently or in the future may be developed by us, including PF690 (pegaspargase), a biosimilar candidate to the reference product Oncaspar. In consideration for the exclusive licenses and other rights contained in the agreement, we received upfront and option payments totaling $15 million in July 2016, and may be eligible to receive additional payments of up to $166 million based on the achievement of certain development, regulatory, and sales-related milestones, including up to $41 million for certain non-sales-related milestones. We may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration.

The prospects for the product candidates developed under these collaborations depend on the expertise, development and commercial skills, and financial strength of Strides Arcolab and Jazz, respectively. Our collaborations with Strides Arcolab, Jazz or any future collaboration partner may not be successful, and we may not realize the expected benefits from such collaborations, due to a number of important factors, including but not limited to the following:

- Strides Arcolab, Jazz or any future collaboration partner may terminate their agreements with us prior to completing development or commercialization of our product candidates, in whole or in part, adversely impacting our potential approval and revenue from licensed products;
- the timing and amount of any payments we may receive under these agreements will depend on, among other things, the efforts, allocation of resources, and successful commercialization of the relevant

product candidates by Strides Arcolab, Jazz or any future collaboration partner, as applicable, under our agreements;

- the timing and amounts of expense reimbursement that we may receive are uncertain; or
- Strides Arcolab, Jazz or any future collaboration partner may change the focus of their development or commercialization efforts or pursue or emphasize higher priority programs.

A failure of Strides Arcolab, Jazz or any future collaboration partner to successfully develop our product candidates which are covered by the collaboration, or commercialize such product candidates, or the termination of our agreement with Strides Arcolab, Jazz or any future collaboration partner, as applicable, may have a material adverse effect on our business, results of operations and financial condition.

Our existing product development and/or commercialization arrangements, and any that we may enter into in the future, may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We are a party to, and continue to seek additional, collaboration arrangements with other pharmaceutical companies for the development and/or commercialization of our current and future product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing, both in the United States and internationally.

To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaboration partners. Any failure to meet our clinical milestones with respect to an unpartnered product candidate would make finding a collaboration partner more difficult. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we cannot guarantee that we can successfully maintain such relationships or that the terms of such arrangements will be favorable to us. If we fail to establish and implement collaboration or other alternative arrangements, the value of our business and operating results will be adversely affected.

We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements. The terms of any collaboration or other arrangements that we may establish may not be favorable to us. The management of collaborations may take significant time and resources that distract our management from other matters. Our ability to successfully collaborate with any future collaboration partners may be impaired by multiple factors including:

- a collaboration partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaboration partner may cease development in therapeutic areas which are the subject of alliances with us;
- a collaboration partner may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payments tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our current or future products, if any;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;

- a collaboration partner may exercise its rights under the agreement to terminate our collaboration;
- a dispute may arise between us and a collaboration partner concerning the research or development of a product candidate or commercialization of a product resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- the results of our clinical trials may not match our collaboration partners' expectations, even if statistically significant;
- a collaboration partner may not adequately protect or enforce the intellectual property rights associated with a product or product candidate; and
- a collaboration partner may use our proprietary information or intellectual property in such a way as to invite litigation from a third party.

Any such activities by our current or future collaboration partners could adversely affect us financially and could harm our business reputation.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally, or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

We rely on CROs to conduct and oversee our planned clinical trials for our product candidates and other clinical trials for product candidates we are developing or may develop in the future. If our CROs do not successfully carry out their contractual duties, meet expected deadlines, or otherwise conduct the trials as required or comply with regulatory requirements, we and our collaboration partners may not be able to seek or obtain regulatory approval for or commercialize our product candidates when expected or at all, and our business could be substantially harmed.

We will continue to rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and in accordance with applicable legal and regulatory requirements. These third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, there is no guarantee that any such third party will devote adequate time and resources to our clinical trial. If our CRO or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of, seek or obtain regulatory approval for, or successfully commercialize our product candidates. We plan to rely heavily on these third parties for the execution of clinical trials for products we are developing or may develop in the future, and will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on our CRO does not relieve us of our regulatory responsibilities.

We, our CRO and our collaboration partners are required to comply with Good Clinical Practice, or GCP, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical

development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we, our CRO or our collaboration partners fail to comply with applicable GCP regulations, the clinical data generated in clinical trials may be deemed unreliable and submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before accepting our applications for review or approving marketing applications. We cannot assure that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, clinical trials must be conducted with product produced under current Good Manufacturing Practices, or cGMP, regulations, which are enforced by regulatory authorities. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if our CRO violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Comparative clinical trials require a substantial number of patients that can form the basis for generating statistically significant results. Delays in site initiation or unexpectedly low patient enrollment rates may delay the results of the clinical trial. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. Further, if our relationship with our CRO is terminated, we may be unable to enter into arrangements with an alternative CRO on commercially reasonable terms, or at all. Switching or adding CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition or results of operations.

We rely on third parties, and in some cases a single third party, to manufacture nonclinical and clinical supplies of our product candidates and to store critical components of our product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product candidates, or fail to do so at acceptable quality levels or prices.

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates for use in clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on third-party manufacturers, including our collaboration partners, Strides Arcolab and Jazz, to manufacture our product candidates for preclinical and clinical studies. Successfully transferring complicated manufacturing techniques to manufacturing organizations and scaling up these techniques for commercial quantities will be time consuming and we may not be able to achieve such transfer. Moreover, the market for contract manufacturing services for protein therapeutics is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we generally do not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing, and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions,

civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that are being developed could delay, prevent or impair clinical development or commercialization efforts. If our manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any manufacturer that we engage may need to increase manufacturing capacity. If we or our manufacturers are unable to produce our product candidates in sufficient quantities to meet the requirements for the launch of these products or to meet future demand, our revenue and gross margins could be adversely affected. Although we currently believe that we and our manufacturers will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

We also rely on third parties to store master and working cell banks for our product candidates. We have master and working cell banks and believe we would have adequate backup should any cell bank be lost in a catastrophic event. However, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks, which could materially and adversely affect our business, financial condition and results of operations.

We rely on third-party suppliers, and in some instances a single third-party supplier, for the manufacture and supply of certain materials in our protein production services, and these suppliers could cease to manufacture the materials, go out of business or otherwise not perform as anticipated.

We rely on third-party suppliers for our protein production services and in some instances a single third-party supplier, for the manufacture and supply of certain materials. We currently rely, and expect to continue to rely, on a single-source supplier for the manufacture and supply of CRM197. To meet these demands, our supplier is in the process of increasing production capacity, and we also have established a repository in the United States that is capable of storing a safety supply of CRM197 and the CRM197 cell bank. Furthermore, we have taken steps to identify alternate sources of supply sufficient to support future needs; however, there may be delays in switching to these alternative suppliers if our contract with primary sources are terminated without notice. Regardless of the foregoing alternative measures, we cannot guarantee that we will have an adequate supply of CRM197. If we are unable to secure adequate quantities of CRM197 from our primary supplier, from potential secondary suppliers or from our safety supply, we may be required to identify additional suppliers. If we are required to engage additional suppliers, we may not be able to enter into an alternative supply arrangement on commercially reasonable terms, or at all. Even if we are able to identify additional suppliers and enter into agreements on commercially reasonable terms, we may incur delays associated with identifying and qualifying additional suppliers and negotiating the terms of any supply contracts. These delays could adversely impact our business and negatively affect profitability of our protein production services.

We have entered into collaborations with third parties in connection with the development of certain of our product candidates. Even if we believe that the development of our technology and product candidates is promising, our partners may choose not to proceed with such development.

Our existing agreements with our collaboration partners, including our agreements with Strides Arcolab and Jazz, are generally subject to termination by the counterparty on short notice upon the occurrence of certain

circumstances. Accordingly, even if we believe that the development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, such as the termination of our collaboration with Pfizer in August 2016, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us.

We are also at risk that our collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial and cash flow difficulties that force them to limit or reduce their participation in our joint projects;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- our collaboration partners may terminate their collaboration with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

If we cannot maintain successful collaborations, our business, financial condition and operating results may be adversely affected.

If we are unable to maintain our commercial supply agreements with key customers purchasing CRM197 or if third-party distributors of our reagent proteins fail to perform as expected, sales revenue could decline.

We primarily sell CRM197 directly to biopharmaceutical companies and currently have several commercial supply agreements in place for long-term supply of CRM197. To establish and maintain relationships with customers, we believe we need to maintain adequate supplies of CRM197, remain price competitive, comply with regulatory regulations and provide high quality products. If we are unable to establish and maintain arrangements for the sale of CRM197, our revenue and profits would decline.

Although we sell our protein reagents through multiple sales channels, including our ecommerce website, we also sell our protein reagents to some of our customers through third-party distributors. Many of such third parties also market and sell products from our competitors. Our third-party distributors may terminate their relationships with us at any time, or with short notice. Our future performance will also depend, in part, on our ability to attract additional third-party distributors that will be able to market protein reagents effectively, especially in markets in which we have not previously distributed our protein reagents. If our current third-party distributors fail to perform as expected, our revenue and results of operations could be harmed.

Risks Relating to Our Intellectual Property

Our collaboration partners may assert ownership or commercial rights to inventions we develop from our use of the materials which they provide to us, or otherwise arising from our collaboration.

We collaborate with several companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing and/or commercial rights to any inventions that result from our use of any third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's materials, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether.

If our efforts to protect our intellectual property related to our platform technology and our current or future product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our current product candidates and our development programs. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform and product candidates. However, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patentability of inventions, and the validity, enforceability and scope of patents in the biotechnology and pharmaceutical industry involve complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the United States or foreign countries. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We may be unaware of certain prior art relating to our patent applications and patents, which could prevent a patent from issuing from a pending patent application, or result in an issued patent being invalidated. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to commercialize our current or future product candidates, and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market our current or future product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates, or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party.

The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

In addition to the protection afforded by patents, we also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents.

As part of our efforts to protect our trade secrets and other confidential information, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. We also note in this respect that trade secret protection in foreign countries may not provide protection to the same extent as federal and state laws in the United States. A breach of confidentiality could significantly affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Also, third parties, including our competitors, may independently develop substantially equivalent proprietary information and technologies or otherwise lawfully gain access to our trade secrets and other confidential information. In such a case, we would have no right to prevent such third parties from using such proprietary information or technologies to compete with us, which could harm our competitive position.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Our competitors have developed large portfolios of patents and patent applications in fields relating to our business and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product

candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the European Union member States seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our biosimilar or vaccine products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third-party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third-party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We may not be able to globally protect our intellectual property rights.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets of former or other employers.

Many of our employees and consultants, including our senior management, have been employed or retained by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or consultant's former or other employer. We are not aware of any material threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Government Regulation

The approval processes of the FDA, EMA, and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we and our collaborators are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting, and export and import of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and EEA Competent Authorities in the EEA, and by other regulatory authorities in other countries, which regulations differ from country to country. Neither we nor any collaboration partner is permitted to market PF708, PF582 or any future product candidates in the United States until approval from the FDA is received, or in the EEA until we receive EU Commission or EEA Competent Authority approvals. The time required to obtain approval from regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of such regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We and our collaboration partners have not submitted any market application to regulatory authorities or obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a biologics license application, or BLA; a new drug application, or NDA, under the 505(b)(2) section of the Food, Drug, and Cosmetic Act; a biosimilar product application under the 351(k) pathway of the PHSA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA, or other submission or to obtain regulatory approval in the United States, the EEA, or elsewhere;
- regulatory authorities may disagree with the design or implementation of our clinical trials and may, at any time, determine that the regulatory pathway that we have committed to for PF708, PF582 or any future product candidate is inappropriate;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- the approval policies or regulations of regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to seek or obtain regulatory approval to market PF708, PF582 or any other product candidates, which would significantly harm our business, results of operations and prospects. Moreover, any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing.

In addition, even if we or our collaborators were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than requested, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we or our collaborators fail to obtain approval for our two most advanced product candidates or if our two most advanced product candidates are not commercially successful, we may have to curtail our product development programs and our business would be materially harmed.

We have invested a significant portion of our time, financial resources and efforts in the development of our two most advanced product candidates, PF708 and PF582. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely and successful completion of all necessary clinical trials and our immunogenicity/ pharmacokinetic study in subjects with osteoporosis for PF708, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third-party contractors, including our collaborators;
- our ability to find a suitable collaboration partner to develop PF582 or our ability to obtain substantial additional sources of funding to develop PF582 as currently contemplated;

- timely receipt of necessary marketing approvals from the FDA, the EU Commission, and similar foreign regulatory authorities;
- maintaining an acceptable safety and adverse event profile of our products following approval;
- achieving and maintaining compliance with all regulatory requirements applicable to our product candidates or any approved products;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity, where available, for our product candidates;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors; and
- the ability to raise additional capital on acceptable terms to achieve our goals.

If we and our collaboration partners are unable to seek and obtain regulatory approval for any of our product candidates in a timely manner or at all, we may never realize revenue from these products and we may have to curtail our other product development programs. As a result, our business, financial condition and results of operations would be materially harmed.

Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262, or the BPCIA, created an elaborate and complex patent dispute resolution mechanism for biosimilars that could prevent us from launching our product candidates in the United States or could substantially delay such launches. The BPCIA mechanism required for 351(k) biosimilar applicants may pose greater risk as compared to the litigation risk to which we might be exposed under a traditional 351(a) BLA regulatory pathway.

The BPCIA sets forth patent disclosure and briefing that are demanding and time-sensitive. The following is an overview of the patent exchange and patent briefing procedures set forth in the BPCIA:

- Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a 351(k) biosimilar applicant must provide a copy of its application to the originator.
- Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator which it believes could be asserted against the biosimilar applicant.
- Statement by the Biosimilar Applicant. Following the receipt of the originator's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand-name firm could assert against the reference product.

- Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
- Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand-name firm must bring an action for patent infringement within 30 days.
- Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent.
- Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list. The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.
- Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified, but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion.

Biosimilar companies such as ours have the option of applying for U.S. regulatory approval for our products under either a traditional 351(a) BLA approval route, or under the recently enacted streamlined 351(k) approval route established by the BPCIA. The factors underpinning such a decision are extremely complex and involve, among other things, balancing legal risk (in terms of, e.g., the degree and timing of exposure to potential patent litigation by the originator) versus regulatory risks (in terms of, e.g., the development costs and the differing scope of regulatory approval that may be afforded under 351(a) versus 351(k)).

A significant legal risk in pursuing regulatory approval under the 351(k) regulatory approval route is that the above-summarized patent exchange process established by the BPCIA could result in the initiation of patent infringement litigation prior to FDA approval of a 351(k) application, and such litigation could result in blocking the market entry of our products. In particular, while the 351(k) route is more attractive to us (versus 351(a)) for reasons related to development time and costs and the potential broader scope of eventual regulatory approval for our proposed biosimilar candidates, the countervailing risk in such a regulatory choice is that the complex patent exchange process mandated by the BPCIA could ultimately prevent or substantially delay us from launching our products in the United States.

Moreover, the disclosure process set forth in Step 1 of the process outlined above, which is directed to disclosure by the biosimilar applicant of not only its regulatory application but also the applicant's manufacturing process, has the potential to afford originators an easier path than traditional infringement litigation for developing any factual grounds they may require to support allegations of infringement. The rules established in the BPCIA's patent dispute procedures (versus the rules governing traditional patent infringement litigation) place biosimilar firms at a significant disadvantage by affording originators a much easier mechanism for factual discovery, thereby increasing the risk that a biosimilar product could be blocked from the market more quickly than under traditional patent infringement litigation processes.

Preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure such legal support if large, well-funded originators have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long standing relationships with originators. Furthermore, we could be at a serious disadvantage in this process as an originator company, as competitors may be able to apply substantially greater legal and financial resources to this process than we could.

We are aware that some biosimilar companies, namely Sandoz International GmbH, or Sandoz, a subsidiary of Novartis AG, and Celltrion, Inc. have engaged in legal challenges against originators to establish their right to bring declaratory judgment actions against such originators outside the complex framework of the BPCIA patent exchange rules in order to challenge the validity of the originators' patents *prior* to the filing of any biosimilar regulatory application. For example, in the Sandoz case against the originator Amgen (relating to Sandoz' proposed etanercept (Enbrel) biosimilar) the federal district court ruled that Sandoz did not have the right to bring a declaratory judgment action against Amgen to challenge the validity of certain Amgen-controlled patents directed to Enbrel, but instead determined that Sandoz must use the patent exchange mechanism established in the BPCIA. Sandoz appealed this decision to the United States Court of Appeals for the Federal Circuit, and on December 5, 2014 the Federal Circuit Court ruled that Sandoz had not met the legal requirements to pursue a declaratory judgment action against Amgen. The Federal Circuit court did not address whether the patent resolution mechanism established in the BPCIA would preclude Sandoz from filing its declaratory judgment action against Amgen if and when it files an FDA application under the BPCIA for its etanercept biosimilar.

In October 2014, Amgen filed suit in federal district court against Sandoz alleging that Sandoz unlawfully refused to follow the patent resolution provisions of the BPCIA in connection with Sandoz' July 2014 regulatory approval application under 351(k) for its Neupogen (filgrastim) biosimilar, Zarxio. Amgen sought declaratory and injunctive relief. In October 2014, Amgen also filed a Citizen's Petition with the FDA asking that the FDA require biosimilar applicants to comply with the BPCIA by providing to the reference product sponsor a copy of the biosimilar application accepted for review, together with information that fully describes the manufacture of the proposed biosimilar product, within 20 days after being informed by the FDA that the biosimilar application has been accepted for review. On March 19, 2015, the district court refused Amgen's request to enjoin Sandoz' launch of Zarxio and ruled that the patent resolution provisions of the BPCIA (summarized in the prior eight bullet points) are optional insofar as it is permissible for a 351(k) applicant to decide not to provide its BLA and/or manufacturing information to the originator. The court also held that a biosimilar applicant need not wait until it receives BLA approval to provide the 180 prior day notice of commercial marketing set forth in the BPCIA provisions (see paragraph 8 above), but instead may provide such notice to the originator, if at all, prior to receiving FDA approval. On March 26, 2015, the FDA denied Amgen's Citizen's Petition. On July 21, 2015, a divided panel of the Federal Circuit issued its first decision interpreting the BPCIA on appeal in the *Amgen* v. *Sandoz* case. The court held that a biosimilar applicant is not required to share its biosimilar application with the reference product sponsor or follow the patent dispute resolution procedures set forth in the BPCIA. However, the Federal Circuit appellate court also held that the biosimilar applicant must provide 180 days pre-marketing notice and cannot do so until after the FDA has "licensed" (approved) the biosimilar product. On February 16, 2016, Sandoz petitioned the United States Supreme Court for certiorari review of this latter holding.

If we file a 351(k) regulatory approval application for one or more of our products, we may consider it necessary or advisable to adopt the strategy of selecting one or more patents of the originator to litigate in the above described BPCIA process (for example in steps 3 and 7, of the process, as outlined above), either to assert our non-infringement of such patents or to challenge their validity; but we may ultimately not be successful in that strategy and could be prevented from marketing the product in the United States.

Under the complex and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our products in the United States.

Our ability to market our therapeutic equivalent products in the United States may be significantly delayed or prevented by the Hatch-Waxman patent dispute resolution mechanism, including a potential automatic 30 month stay of regulatory approval of our marketing applications.

The Hatch-Waxman Act. The provisions of Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FFDCA, were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug; the section gives the FDA express permission to rely on data not developed by the New Drug Application, or NDA, applicant. Indeed, an NDA filed under Section 505(b)(2) is one for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. We are pursuing a Section 505(b)(2) regulatory strategy for our PF708 product candidate and we plan to reference the Forteo (teriparatide) listed drug which is marketed by Eli Lilly for the treatment of osteoporosis. It is possible that for one reason or another, we will not be able to establish that our PF708 product candidate is suitable for approval under the Section 505(b)(2) framework. In addition, to the extent we rely on certain data and information that was submitted to the FDA related to the safety of Forteo, the FDA may likely require any approved labeling for PF708 to include certain safety information that is included in the Forteo label, including contraindications, warnings, precautions and other safety information.

The owner of an NDA for a branded drug product may list with the FDA certain patents whose claims allegedly cover the applicant's branded product. Each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, referred to as a Paragraph I Certification; (2) such patent has expired, referred to as a Paragraph II Certification; (3) the date on which such patent expires, referred to as a Paragraph III Certification; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted, referred to as a Paragraph IV Certification.

The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. An applicant submitting a Paragraph IV Certification must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved branded drug to which the 505(b)(2) application references. If the reference branded drug holder and patent owners file a lawsuit directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV Certification notice, the FDA is prohibited from approving the 505(b)(2) application until the earlier of 30 months from the receipt of the Paragraph IV Certification, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. In the event we commercially launch our PF708 product candidate at a time when one or more unexpired patents are listed in the Orange Book for a reference listed drug product, we see substantial risk that the Paragraph IV certification process, including the likelihood of imposition of a 30 month stay and necessity of defending against accusation of patent infringement, may significantly delay or defeat our ability to competitively market our PF708 product in the United States.

Non-Patent Exclusivity and Approval of Competing Products. Additionally, a 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the NDA branded reference drug has expired as described in further detail below. Market and data exclusivity provisions under the FFDCA can delay the submission or the approval of certain applications for competing products. In addition to patent exclusivity, the holder of the NDA for a reference listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve another drug application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any application for the same active moiety and that relies on the FDA's findings regarding that

drug; the FDA may accept an application for filing after four years if the 505(b)(2) applicant makes a Paragraph IV Certification. A drug may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA that references such product until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the entire exclusivity period.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials for our product candidates. While we have agreements governing the committed activities of our collaborators and CROs, we have limited influence over their actual performance. A failure of one or more clinical trials can occur at any time during the trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates that have shown promising results in early studies may still suffer significant setbacks in subsequent clinical studies. For example, the results generated to date in the clinical trial for PF582 do not ensure that later clinical trials will demonstrate similar results. There is a high failure rate for drugs and biologics proceeding through clinical studies, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if the clinical trials for our product candidates are completed, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and the results may not be sufficient to obtain regulatory approval for our product candidates.

We have in the past and may in the future experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of human clinical studies;
- raise sufficient capital to fund a trial;
- obtain regulatory approval, or feedback on trial design, necessary to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;
- identify, recruit, and enroll suitable patients to participate in a trial;
- have patients complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;

- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities of product candidate for use in clinical trials; and
- avoid delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies, or the inability to do any of the foregoing.

Patient enrollment is a significant factor in the completion of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the data safety monitoring board, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenue from any of these product candidates will be delayed. In addition, any delays in completing clinical trials for our product candidates will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Even if PF708, PF582 or any of our other product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.

Even if we or our collaboration partners obtain FDA or other regulatory approvals, PF708, PF582 or any of our other product candidates may not achieve market acceptance among physicians and patients, and may not be commercially successful. The degree and rate of market acceptance of PF708, PF582 or any of our other product candidates for which we receive approval depends on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- proper training and administration of our products by physicians and medical staff;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of physicians and patients;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events; and

- the effectiveness of our sales and marketing efforts.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue and continue our business.

The development, manufacture and commercialization of biosimilar and other therapeutic equivalent products pose unique risks, and our failure to successfully introduce biosimilar and other therapeutic equivalent products could have a negative impact on our business and future operating results.

We are actively working to develop multiple biosimilar and other therapeutic equivalent products, including our two most advanced product candidates, PF708 and PF582. The cost to develop each biosimilar and therapeutic equivalent product candidate could vary significantly and is highly dependent on the specific compound and the amount and type of clinical work that will be necessary for regulatory approval. There can be no assurance that our clinical work will be successful, or that regulatory authorities will not require additional clinical development beyond that which we have planned. Additionally, we may enter into alliances and collaborations to fund biosimilar and therapeutic equivalent product research and development activities, and the success of any such biosimilar or therapeutic equivalent product program may depend on our ability to realize the benefits under such arrangements. Due to events beyond our control or the risks identified herein, we may be unable to fund all or some of our internal biosimilar and therapeutic equivalent product research and development initiatives, which would have an adverse impact on our strategy and growth initiatives.

We intend to pursue market authorization globally when commercially appropriate. Since October 2005, the European Union has had a regulatory framework for the approval of biosimilar products. As of December 31, 2016, 25 biosimilar medicinal products, less three subsequently withdrawn, have been approved. In the United States, an abbreviated pathway for approval of biosimilar products was established by the BPCIA, enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. The BPCIA established this abbreviated pathway under section 351(k) of the Public Health Service Act, or PHSA. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications. However, to date, only four biosimilars have been approved by the FDA, and no biosimilar product has been designated as interchangeable to the reference drug. Moreover, market acceptance of biosimilar products in the U.S. is unclear. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for biological products already licensed by the FDA pursuant to BLAs, or "reference products." Market success of biosimilar products will depend on demonstrating to patients, physicians, payors, and relevant authorities that such products are safe and efficacious compared to other existing products.

We will continue to analyze and incorporate into our biosimilar development plans any final regulations issued by the FDA, pharmacy substitution policies enacted by state governments, and other applicable requirements established by relevant authorities. The costs of development and approval, along with the probability of success for our biosimilar product candidates, will be dependent upon application of any laws and regulations issued by the relevant regulatory authorities.

Biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which will likely delay and could prevent the commercial launch of a product. Moreover, the BPCIA prohibits the FDA from accepting an application for a biosimilar candidate to a reference product within four years of the reference product's licensure by the FDA. In addition, the BPCIA provides innovative biologics with twelve years of exclusivity from the date of their licensure, during which time the FDA cannot approve any application for a biosimilar candidate to the reference product. For example, the FDA may not be able to approve any application that we or our collaborators submit for PF582 until twelve years after the original BLA for Lucentis was approved. However, in his proposed budget for fiscal year 2014, President Obama proposed to cut this 12-year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity due

to minor changes in product formulations, a practice often referred to as "evergreening." It is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning is subject to significant uncertainty. Future implementation decisions by the FDA could result in delays in the development or commercialization of our product candidates or increased costs to assure regulatory compliance, and could adversely affect our operating results by restricting or significantly delaying our ability to market new biosimilar products. In the EEA, holders of marketing authorizations of reference products (for which a marketing authorization was applied for under the centralized procedure after November 20, 2005, or under the Decentralized, Mutual Recognition and national procedures, after October 30, 2005) enjoy eight years of data exclusivity during which a follow-on product or biosimilar marketing authorization applicant cannot rely on the preclinical and clinical data included in the reference product's dossier, and ten years of marketing exclusivity during which a follow-on product or biosimilar of the reference product cannot be placed in the EEA market. The marketing exclusivity period can be extended one additional year (to 11 years) if a second indication of the reference product with significant clinical benefit is approved during the eight-year data exclusivity period. The data and marketing exclusivity periods start from the date of the initial authorization, which for reference medicinal products authorized through the Centralized Procedure is the date of notification of the marketing authorization decision to the marketing authorization holder of the reference product. Lucentis was granted a marketing authorization by the EU Commission through the EU centralized procedure on January 22, 2007.

We may rely on the Animal Rule in conducting trials, which could be time consuming and expensive.

To obtain FDA approval for our vaccine candidate Px563L, we may obtain clinical data from trials in healthy human subjects that demonstrate adequate safety, and efficacy data from adequate and well-controlled animal studies under regulations issued by the FDA in 2002, often referred to as the "Animal Rule." Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. If we use this approach we may not be able to sufficiently demonstrate this correlation to the satisfaction of the FDA, as these corollaries are difficult to establish and are often unclear. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, seeking approval under the Animal Rule may add significant time, complexity and uncertainty to the testing and approval process. The FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve Px563L, or place restrictions on our ability to commercialize the products. In addition, products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients. Further, regulatory authorities in other countries have not, at this time, established an "Animal Rule" equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the U.S. and internationally may have the capability to test animals involving exposure to anthrax or otherwise assist us in qualifying the requisite animal models, and we must compete with other companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.

If we and our collaboration partners are not able to demonstrate biosimilarity of our biosimilar product candidates to the satisfaction of regulatory authorities, we will not obtain regulatory approval for commercial sale of our biosimilar product candidates and our future results of operations would be adversely affected.

Our future results of operations depend, to a significant degree, on our and our collaboration partners' ability to obtain regulatory approval for and commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other things, that our proposed biosimilar products are highly

similar to biological products already licensed by the FDA pursuant to Biologic License Applications, or BLAs, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. In the EEA, the similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy. For example, a determination of biosimilarity for PF582 will be based on our demonstration of its high similarity to Lucentis.

In addition, the FDA may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted by a pharmacist for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of biosimilarity or interchangeability, regulatory authorities may require additional confirmatory information beyond what we and our collaboration partners plan to initially submit in our applications for approval, such as more in-depth analytical characterization, animal testing, or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive. We cannot predict whether any of our biosimilar product candidates will meet regulatory authority requirements for approval as a biosimilar or interchangeable product. To date, the FDA has not approved a biosimilar product as being interchangeable to the reference drug.

Analytical assessments can identify potential differences between biosimilar candidates and reference products. Differences in the analytical assessments may require clinical studies to reduce the residual uncertainties. In the event that regulatory authorities require us to conduct additional clinical trials or other lengthy processes, the commercialization of our proposed biosimilar products could be delayed or prevented. Delays in the commercialization of, or the inability to obtain regulatory approval for, these products could adversely affect our operating results by restricting or significantly delaying our introduction of new biosimilars.

If other biosimilars of Lucentis or other therapeutic equivalent products to Forteo are approved and successfully commercialized before PF708 or PF582, our business would suffer.

Other companies may seek approval to manufacture and market biosimilar versions of Lucentis or therapeutic equivalent product versions of Forteo. If other biosimilars of Lucentis or therapeutic equivalent product versions of Forteo, are approved and successfully commercialized before PF708 or PF582, we may never achieve significant market share for PF708 or PF582, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer. In addition, the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that reference product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). A determination that another company's product is interchangeable with Lucentis prior to approval of PF582 may therefore delay the potential determination that PF582 is interchangeable with the reference product, which may materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

Failure to obtain regulatory approval in each regulatory jurisdiction would prevent us and our collaboration partners from marketing our products to a larger patient population and reduce our commercial opportunities.

In order to market our products in the European Union, the United States and other jurisdictions, we or our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The European Medicines Agency is responsible for the centralized procedure for human medicines. This procedure results in a single marketing authorization that is valid in all European Union countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within the United States or in any market outside the United States. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations.

Even if we and our collaboration partners obtain regulatory approvals for our product candidates, we will be subject to ongoing regulatory review.

Even if we and our collaboration partners obtain regulatory approval for our product candidates, any products we develop will be subject to ongoing regulatory review with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our contract manufacturers will be subject to continual and unannounced review and inspections by the regulatory authorities governing the markets in which we wish to sell our products. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we and our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the safety and efficacy or the safety, purity, and potency of the product candidate. We will be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. Any new legislation addressing drug or biologic product safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We and our collaboration partners will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug and biologic products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, 351(k) application or marketing authorization application, or MAA, must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees

with the promotion, marketing or labeling of a product, or if we or our collaboration partners fail to comply with applicable continuing regulatory requirements, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or our collaboration partners fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may subject us to administrative or judicially imposed sanctions or other actions, including, among other things:

- adverse publicity, fines or warning letters;
- civil or criminal penalties;
- injunctions;
- suspending or withdrawing regulatory approval;
- suspending any of our ongoing clinical studies;
- refusing to approve pending applications or supplements to approved applications submitted by us;
- imposing restrictions on our operations, including closing our contract manufacturers' facilities; or
- seizing or detaining products, or requiring a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We will also be subject to various health care fraud and abuse laws, including anti-kickback, false claims and fraud laws, and physician payment transparency laws, and any violations by us of such laws could result in fines or other penalties.

Although we currently do not have any products on the market, if our product candidates are approved and we begin commercialization, we will be subject to healthcare regulation and enforcement by the federal government and the states and EEA and other foreign governments in which we conduct our business. These laws include, without limitation, state and federal, as well as EEA and other foreign, anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations. The federal Anti-Kickback Statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties. The FCA imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in

its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. If our future marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenue could be adversely affected, which would likely harm our business, financial condition, and results of operations.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposed new reporting requirements on drug commercial manufacturers for payments and other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers must submit reports by the 90th day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure investors that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory approval of PF708, PF582 or any future product candidates and to produce, market, and distribute our products after approval is obtained, if any.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacturing, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for PF708, PF582 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;

- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

If efforts by manufacturers of reference products to delay or limit the use of biosimilars and therapeutic equivalent products are successful, our sales of biosimilar and other therapeutic equivalent products may suffer.

Many manufacturers of reference products have increasingly used legislative, regulatory and other means in attempts to delay regulatory approval of and competition from biosimilars and therapeutic equivalent products. These efforts have included sponsoring legislation to prevent pharmacists from substituting biosimilars and therapeutic equivalent products for prescribed reference products or to make such substitutions more difficult by establishing notification, recordkeeping, and/or other requirements, as well as seeking to prevent manufacturers of biosimilars and therapeutic equivalent products from referencing the branded products in biosimilar and therapeutic equivalent product labels and marketing materials. If these or other efforts to delay or block competition are successful, we may be unable to sell our biosimilar and therapeutic equivalent product candidates, which could have a material adverse effect on our sales and profitability.

Our and our collaboration partners' future sales will be dependent on the availability and level of coverage and reimbursement from third-party payors who continue to implement cost-cutting measures and more stringent reimbursement standards.

In the United States and internationally, our and our collaboration partners' ability to generate revenue on future sales of our products will be dependent, in significant part, on the availability and level of coverage and reimbursement from third-party payors, such as state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. In addition, particularly in the U.S. and increasingly in other countries, we will be required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities.

In addition, in the United States, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The Affordable Care Act, among other things, subjected biologic products to potential competition by lower-cost biosimilars and follow-on products, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable reference product drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by

Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Tax Payer Relief Act, or ATRA, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare products and services, which could result in reduced demand for our products, if approved, or additional pricing pressures. Furthermore, the current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on biosimilar manufacturing industry as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

Foreign governments tend to impose strict price controls, which may adversely affect our revenue, if any.

In some foreign countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Our existing or future collaboration partners, if any, may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals which could adversely affect our revenues and profits. To obtain reimbursement or pricing approval in some countries, we or our collaboration partners may also be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Risks Relating to Owning Our Common Stock

The market price of our stock may fluctuate significantly, and investors may have difficulty selling their shares.

Our stock is currently traded on NYSE MKT, but we can provide no assurance that we will be able to maintain an active trading market on NYSE MKT or any other exchange in the future. The trading volume of our stock tends to be low relative to our total outstanding shares, and we have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. As of December 31, 2016, we had 23,429,501 shares of common stock outstanding, and stockholders holding at least 5% of our stock, individually or with affiliated persons or entities, collectively beneficially owned or controlled approximately 56% of such shares. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our relatively small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline.

Since shares of our common stock were sold in our initial public offering in July 2014 at a price of $6.00 per share, our stock price has ranged from $5.28 to $24.41 through December 31, 2016. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this annual report on Form 10-K factors that may cause volatility in our share price include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;

- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- changes to our organization and our search for a permanent chief executive officer;
- commencement of, or our involvement in, litigation;
- market conditions in the relevant market;
- reimbursement or legislative changes in the relevant market;
- failure to complete significant sales;
- regulatory developments that may impact our product candidates;
- any future sales of our common stock or other securities;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general and market prices for the securities of biopharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and will likely continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts publish unfavorable research about our business or cease to cover our business, our stock price and/or trading volume could decline.

The trading market for our common stock may rely, in part, on the research and reports that equity research analysts publish about us and our business. We do not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, the market price of our common stock may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, the market price of our common stock may decline.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could reduce the price that our common stock might otherwise attain and may dilute your voting power and your ownership interest in us.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

As of December 31, 2016, one holder of approximately 2.3 million shares, or approximately 10%, of our outstanding shares, has rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements or prospectus supplements that we file or have filed for ourselves or other stockholders. We also register the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

Furthermore, certain of our executive officers have adopted, and other directors and executive officers may in the future adopt, written plans, known as "Rule 10b5-1 Plans," under which they have contracted, or may in the future contract, with a broker to sell shares of our common stock on a periodic basis to diversify their assets and investments. Sales of substantial amounts of our common stock in the public markets, including, but not limited to, sales made by our executive officers and directors pursuant to Rule 10b5-1 Plans, or the perception that these sales could occur, could cause the market price of our common stock to decline.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups, or JOBS, Act enacted in April 2012, and may remain an "emerging growth company" for up to five years following the completion of our initial public offering, although, if we have more than $1.0 billion in annual revenue, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of December 31 of any year, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31. For as long as we remain an "emerging growth company," we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in our reports filed with the Securities and Exchange Commission, or SEC. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of reporting companies who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. We cannot predict whether investors will find our common stock less

attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

In connection with our audit committee investigation as more fully described in Item 9A, "*Controls and Procedures*", we identified a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that we identified related to a failure to maintain an effective control environment as our former Chief Executive Officer failed to set an appropriate "Tone at the Top." As further described in Item 9A, "*Controls and Procedures*", the material weakness was identified in connection with our Audit Committee Investigation, which found violations of our Board Approval Process Policy and related violations of our Code of Ethics and Conduct by our former Chief Executive Officer. The investigation determined that our former Chief Executive Officer had not acted in accordance with our Board Approval Process Policy and Code of Ethics and Conduct as a result of his failure to comply with certain board approval procedures for third-party contracts.

As further described in Item 9A, "*Controls and Procedures—Remediation Plan and Activities*", we have undertaken steps to improve our internal controls over financial reporting. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities laws and NYSE MKT listing requirements regarding the timely filing of periodic reports, investors may lose confidence in our financial reporting, and our stock price may decline.

Additionally, our independent registered public accounting firm is not required to and did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act due to a transition period established by the rules of the SEC for newly public companies that have not lost their "emerging growth company" status as defined in the JOBS Act. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies amounting to significant deficiencies or material weaknesses may have been identified. We cannot be certain as to when we will be able to implement the requirements of Section 404 of the Sarbanes-Oxley Act. If we fail to implement the requirements of Section 404 in a timely manner, we might be subject to sanctions or investigation by regulatory agencies such as the SEC. In addition, failure to comply with Section 404 or the report by us of a significant deficiency or material weakness may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any significant deficiency or material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our common stock may decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We generated a tax net operating loss for 2016. Our previous tax net operating losses offset the taxable income related to the Pfizer agreement in 2015. The 2016 net operating loss will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period,

the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices including maintaining an effective system of internal control over financial reporting.

As a public company, and increasingly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC, and the NYSE MKT impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to comply with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and changing governance practices.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404(a) of the Sarbanes-Oxley Act requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of Sarbanes-Oxley Act, or Section 404(b), also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. As an "emerging growth company," we are availing ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b). However, we may no longer avail ourselves of this exemption when we are no longer an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404(b) will correspondingly increase. Our compliance with applicable provisions of Section 404 requires us and will continue to require us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, such as the material weakness described in Item 9A, "*Controls and Procedures*," and this could cause a decline in the market price of our stock. Irrespective of any required compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial

reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

Our directors, executive officers and principal stockholders will continue to have substantial control over us and could limit investors' ability to influence the outcome of key transactions, including transactions that would cause a change of control.

As of December 31, 2016, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates beneficially owned or controlled approximately 60% of the outstanding shares of our common stock. Accordingly, these executive officers, directors and stockholders and their respective affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may therefore delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairman of the board of directors, or the chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

We have broad discretion in the use of the net proceeds from our public offerings and may not use them effectively.

We have broad discretion as to how to spend and invest the proceeds from our public offerings, and we may spend or invest these proceeds in a way with which our stockholders disagree. Accordingly, investors will need to rely on our judgment with respect to the use of these proceeds and these uses may not yield a favorable return to our stockholders. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

With the exception of the issuance of shares of common stock to our preferred stockholders in connection with the payment of all accrued and unpaid dividends in connection with our initial public offering, we do not anticipate paying any cash dividends in the foreseeable future.

At the closing of our initial public offering, our board of directors issued shares of common stock to pay all accrued but unpaid dividends on our convertible preferred stock. As of July 29, 2014, there were cumulative unpaid dividends of $7.3 million for our Series A-1 and Series A-2 convertible preferred stock. Based on the initial public offering price of $6.00 per share and the offering closing on July 29, 2014, we issued 1,217,784 shares of common stock to the holders of our outstanding preferred stock prior to the offering in

satisfaction of these accrued dividends through July 28, 2014. With the exception of this dividend, we do not anticipate paying cash dividends on any classes of our capital stock in the foreseeable future. We currently intend to retain our future earnings for the foreseeable future to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain on an investment in our common stock for the foreseeable future.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

As of December 31, 2016, we leased a total of approximately 46,959 square feet of office and laboratory space located at 10790 and 10788 Roselle Street, San Diego, CA 92121. The lease expires on March 31, 2024. We believe that our existing facilities are adequate to meet our business requirements for the foreseeable future and that additional space will be available on commercially reasonable terms, if required.

Item 3. ***Legal Proceedings***

In the normal course of business, we are from time to time involved in legal proceedings or potential legal proceedings, including matters involving employment, intellectual property, or others. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of any currently pending matters would not have a material adverse effect on our business, operating results, financial condition, or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. ***Mine Safety Disclosures*****.**

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information and Holders of Record

Our common stock has been listed on the NYSE MKT under the symbol "PFNX" since July 24, 2014. Prior to that date, there was no public trading market for our common stock. The following table sets forth the high and low sales price per share of our common stock as reported on the NYSE MKT for **the** periods indicated:

	High	Low
Year Ended December 31, 2015:		
First Quarter	$18.72	$ 6.40
Second Quarter	21.01	12.74
Third Quarter	24.41	14.15
Fourth Quarter	18.23	10.87
Year Ended December 31, 2016:		
First Quarter	$12.37	$ 6.50
Second Quarter	11.35	5.79
Third Quarter	10.82	7.06
Fourth Quarter	11.35	7.18

As of February 28, 2017, we had 59 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

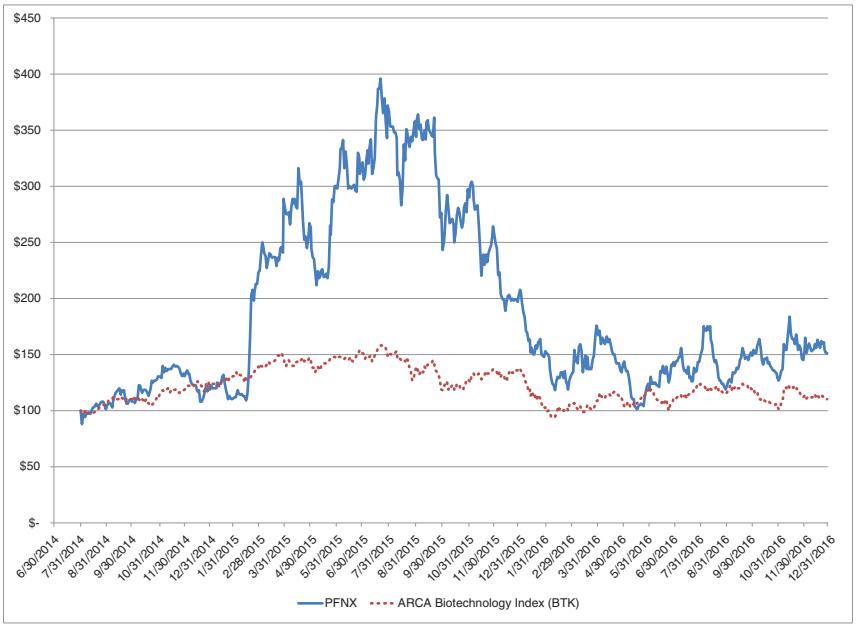
Dividends

With the exception of common stock issued in connection with the payment of all accrued but unpaid dividends upon the conversion of all preferred stock upon the completion of our initial public offering, we have not made any distributions on our common stock and do not intend to make any distributions on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings in the foreseeable future will be used for the operation and growth of our business.

Stock Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or incorporated by reference into any filing of Pfenex Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The graph below shows the cumulative total stockholder return assuming the investment of $100 as of the close on July 24, 2014, the first day of trading for Pfenex Inc.'s common stock, (and the reinvestment of dividends thereafter) in each of (i) Pfenex Inc.'s common stock, and (ii) the ARCA Biotechnology Index. The comparisons in the graph below are based upon historical data and are not indicative of, or intended to forecast, future performance of our common stock or the index. The prices are as of the close of PFNX's first trading day to the close at December 31, 2016.



Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities and Use of Proceeds

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds

In April 2015, we completed a follow-on offering in which we sold 2,610,000 shares of common stock at the public offering price of $15.50 per share. After deducting underwriting discounts and commissions and estimated offering expenses payable by us, the proceeds were approximately $37.3 million. There has been no material change in the planned use of proceeds from our public offering as described in our final prospectus filed with the SEC on April 24, 2015 pursuant to Rule 424(b).

(c) Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the three months ended December 31, 2016.

Item 6. ***Selected Financial Data***

The following selected historical financial data below should be read in conjunction with Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations,*" our financial statements, and the related notes appearing in Item 8, "*Financial Statements and Supplementary Data*", of this Annual Report on Form 10-K to fully understand factors that may affect the comparability of the information presented below.

The consolidated statements of operations data for the years ended December 31, 2016, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016 and 2015 are derived from our audited financial

statements appearing in Item 8, "*Financial Statements and Supplementary Data*," of this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014, 2013 and 2012 are derived from audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in the future.

	Years Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except for per share data)				
Revenues	$60,194	$ 9,583	$10,644	$11,914	$11,294
Expense:					
Cost of revenues[1]	5,313	4,640	7,233	6,423	7,253
Selling, general and administrative	17,340	14,598	9,003	6,698	6,876
Research and development[1]	32,418	18,183	4,125	5,490	1,792
Total expense	55,071	37,421	20,361	18,611	15,921
Income (loss) from operations	5,123	(27,838)	(9,717)	(6,697)	(4,627)
Other income (expense), net	149	74	(77)	(36)	(7)
Income (loss) before income taxes	5,272	(27,764)	(9,794)	(6,733)	(4,634)
Income tax benefit (expense)	209	(452)	—	2,671	2,041
Net income (loss)	$ 5,481	$(28,216)	$ (9,794)	$ (4,062)	$ (2,593)
Effective preferred stock dividends[2]	$ —	$ —	$ —	$ (1,695)	$ (1,589)
Net income (loss) attributable to common stockholders	$ 5,481	$(28,216)	$ (9,794)	$ (5,757)	$ (4,182)
Basic and diluted net income (loss) per share attributable to common stockholders[3]	$ 0.23	$ (1.26)	$ (1.04)	$ (3.76)	$ (2.84)
Basic weighted-average shares used to compute net income (loss) per share attributable to common stockholders	23,389	22,376	9,441	1,531	1,474
Diluted weighted-average shares used to compute net income (loss) per share attributable to common stockholders	23,688	22,376	9,441	1,531	1,474

(1) Please refer to Note 1 of our consolidated financial statements for an explanation of the method used to recognize cost of revenues and research and development expense.

(2) The holders of our convertible preferred stock were entitled to cumulative dividends prior and in preference to our common stock. Because the holders of our convertible preferred stock were entitled to participate in dividends, net loss attributable to common stockholders was equal to net loss adjusted for convertible preferred stock dividends for the period. Immediately upon the closing of our IPO, all outstanding shares of our redeemable convertible preferred stock, or our convertible preferred stock, were automatically converted into an aggregate of 8,634,857 shares of common stock and these holders were issued 1,217,784 shares of common stock for the payment of all accrued and unpaid dividends through July 28, 2014 in connection with such conversion based on the initial public offering price of $6.00 per share and the offering closing on July 29, 2014. See Note 14 to our financial statements for a description of the method used to compute basic and diluted net loss per share attributable to common stockholders and for a description of convertible preferred stock, respectively. Please refer to Note 8 of our consolidated financial statements for an explanation of the cumulative preferred stock dividends.

(3) All share, per-share and related information have been retroactively adjusted, where applicable, to reflect the impact of a 2.812-for-1 reverse stock split, which was effected on June 27, 2014.

Other Financial Data

	As of December 31,				
	2016	2015	2014	2013	2012
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents and short-term investments	$ 81,501	$106,162	$45,722	$ 5,204	$ 9,966
Accounts and unbilled receivables, net	2,822	2,683	1,584	3,461	2,703
Inventory	—	24	23	26	754
Restricted cash	—	3,959	3,955	4,029	1,501
Property and equipment, net	5,246	3,179	2,310	2,329	2,681
Goodwill and intangibles	10,878	11,409	11,940	12,470	13,001
Other	2,675	4,278	5,489	4,294	2,326
Total assets	$103,122	$131,694	$71,023	$ 31,813	$ 32,932
Current liabilities, excluding debt	$ 10,696	$ 6,883	$ 3,762	$ 4,757	$ 3,199
Deferred revenue	12,255	48,095	201	1,253	2,342
Debt	—	3,813	3,813	3,590	1,140
Other	26	1,722	3,373	3,484	3,611
Total liabilities	22,977	60,513	11,149	13,084	10,292
Redeemable convertible preferred stock	—	—	—	113,180	42,500
Stockholders' equity (deficit)	80,145	71,181	59,874	(94,451)	(19,860)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$103,122	$131,694	$71,023	$ 31,813	$ 32,932

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "projections," "business outlook," "estimate," or similar expressions constitute forward-looking statements. Our actual results could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those discussed below, in the section captioned "Risk Factors," and elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biotechnology company engaged in the development of biosimilar and therapeutic equivalent products and other high-value and difficult-to-manufacture proteins. Our product candidate selection strategy is to focus on products with large addressable markets, which are expected to be free of intellectual property barriers in major markets over our projected approval timelines, and for which our *Pf*ēnex Expression Technology® enables efficient and large scale manufacturing. Our pipeline of product candidates and preclinical products under development includes six wholly-owned programs, two that are being developed in a joint venture with Strides Arcolab Limited, a specialty pharmaceutical company, and certain other products that are being developed in collaboration with Jazz Pharmaceuticals Ireland Limited, or Jazz. In addition, we are also developing proprietary vaccine candidates that are being funded by the Department of Health and Human Services and the National Institutes of Health (NIH) within the United States government.

Our lead product candidates include the following:

PF708 – our teriparatide (Forteo) therapeutic equivalent candidate. PF708 is our therapeutic equivalent candidate to Forteo, which is marketed by Eli Lilly and Company for the treatment of osteoporosis. Forteo achieved over $1.4 billion in global product sales in 2015. The PF708 bioequivalence study, conducted in 70 healthy subjects, was completed in the second quarter of 2016 and met its primary objectives. The 90% confidence intervals of the area-under-the-curve (AUC) and maximum concentration (Cmax) geometric mean ratios of PF708 versus Forteo were within the 80-125% range required for concluding bioequivalence. We initiated an immunogenicity/pharmacokinetics study in osteoporosis patients in the fourth quarter of 2016. This study, along with the positive bioequivalence study, is anticipated to satisfy the filing requirements for PF708 through the 505(b)(2) regulatory pathway. The interim pharmacokinetic data from this study is expected in the second half of 2017 and the immunogenicity data is expected in the first half of 2018. We believe that the clinical program in the US may be leveraged for regulatory filings in other geographies, such as the European Union (EU).

PF582 – our ranibizumab (Lucentis) biosimilar candidate. PF582 is our biosimilar candidate to Lucentis, which is marketed by Genentech, Inc., a wholly-owned member of the Roche Group, and Novartis AG, for the treatment of patients with retinal diseases. Lucentis achieved approximately $3.6 billion in global product sales in 2015. In February 2015, we entered into a development and license agreement with Hospira, Inc., or Hospira, a subsidiary of Pfizer Inc. (collectively with Hospira, "Pfizer") for the development and commercialization of PF582. For PF582, we completed a Phase 1/2 trial in patients with wet age-related macular degeneration, or wet AMD, with Pfizer. Following Pfizer's strategic review of the therapeutic focus of its biosimilars pipeline, we entered into a Termination Agreement (the "Termination Agreement") with Pfizer and agreed to terminate the development and license agreement. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred. Under the terms of the Termination Agreement, all rights to PF582 were returned to us in August 2016. In the third quarter of 2016, we announced top-line results from the Phase 1/2 trial, which showed that PF582 was pharmacologically active and with a safety profile that was consistent with that of Lucentis. We enrolled a total of 25 VEGF-inhibitor naïve patients with neovascular AMD (13 received PF582, including one sentinel patient who received open label PF582, 12 received Lucentis). All patients received three monthly intravitreal injections. The primary endpoint of the study was safety and tolerability of PF582 compared to that of Lucentis. There were no clinically meaningful differences in adverse event profiles or intra-ocular pressure between PF582 and Lucentis. The efficacy and pharmacodynamic results indicated that there were no clinically meaningful differences in best corrected visual acuity or decreases in central retinal thickness between PF582 and Lucentis at any of the timepoints.

In addition to our two most advanced product candidates, our pipeline includes various other biosimilar candidates as well as vaccines and next generation biologic candidates. A few of those candidates include the following:

Px563L – our anthrax vaccine candidate funded by BARDA. In August 2016, we announced positive immunogenicity and safety data from Day 70 analysis of the Px563L anthrax vaccine study. The results indicated that the vaccine was well-tolerated and afforded immunogenicity protection with fewer doses than the currently licensed product. The randomized, double-blind, placebo-controlled Phase 1a study enrolled three cohorts in a dose-escalating manner (10 mcg, 50 mcg and 80 mcg of antigen). Within each cohort, subjects received Px563L, RPA563 or placebo in an 8:8:2 ratio. Subjects were administered two doses of vaccine or placebo 28 days apart. Interim results indicated that the vaccine was well-tolerated, with the potential to afford immunogenicity protection against anthrax infection after only two injections (vs. three for currently licensed anthrax vaccine product). Immunogenicity was assessed by toxin-neutralizing antibody (TNA) expressed as 50% neutralizing factor (NF_{50}), with a threshold value ≥ 0.56 correlating with significant survival in animal models of anthrax infection. On Day 70, 100% of Px563L subjects at the 10 mcg and 80 mcg dose levels achieved a TNA $NF_{50} \geq 0.56$, and 87.5% at the 50 mcg dose level achieved the target threshold. An additional success criterion for assessing anthrax vaccine immunogenicity is for the lower confidence limit (LCL), or the lower bound of 95%

confidence interval, of the percentage of subjects who met or exceeded the TNA NF_{50} threshold of 0.56, to be greater than or equal to 40%. On Day 70, all doses of Px563L exceeded this threshold, which was established by the currently licensed anthrax vaccine for the indication of post-exposure prophylaxis. In addition, we have developed a production process for the large scale manufacturing of bulk mrPA. We announced positive interim results from a Phase 1a study in healthy subjects in the second half of 2016, and we anticipate study completion in the first half of 2017.

PF690 – our pegaspargase (Oncaspar) biosimilar candidate. In July 2016, we entered into a license and option agreement with Jazz, pursuant to which we and Jazz will collaboratively develop certain hematology products, and Jazz will have the exclusive right to manufacture and commercialize such products throughout the world. In addition, pursuant to the agreement, we have granted Jazz certain other rights to negotiate the exclusive right to develop, manufacture and commercialize throughout the world other hematology products that are currently or in the future may be developed by us, including PF690 (pegaspargase), a biosimilar candidate to the reference product Oncaspar.

To date, none of our product candidates have completed clinical development, been submitted for regulatory review or received marketing authorization from any regulatory agency, and therefore we have not received revenue from the sale of any of our product candidates.

Our product candidates are enabled by our patented protein production platform, *Pf*ēnex Expression Technology®, which we believe confers several important competitive advantages compared to traditional techniques for protein production, including the ability to produce complex proteins with higher accuracy and greater degree of protein purity, as well as speed and cost advantages. The development of proteins, such as biosimilars, requires several competencies which represent both challenges and barriers to entry. Due to their inherent complexity, proteins require the use of living organisms to efficiently produce them at a large scale. Traditional techniques for protein production employ a trial and error approach to production organism, or strain, selection and process optimization, which is inherently inefficient and typically produces suboptimal results. This historically inefficient process provides barriers to create or replicate complex proteins, adds significant time to market and results in the high cost of goods typical of biologic therapeutics. Together, these limitations pose significant hurdles for companies interested in entering the market with biosimilar and therapeutic equivalents to branded products. Our platform utilizes a proprietary high throughput robotically-enabled parallel approach, which allows the construction and testing of thousands of unique protein production variables in parallel, thereby allowing us to produce and characterize complex proteins while reducing the time and cost of development and long-term production.

Transparency Market Research states that the global biologics market will expand at a healthy 10.9% compound annual growth rate from 2016 to 2024. If the number holds true, the market, which is valued at $210 billion in 2016, is expected to rise to $480 billion by 2024. We believe the emerging biosimilar market will be significant due to the large number of blockbuster products expected to lose patent protection in the next several years, abbreviated regulatory pathways for the approval of biosimilars and a mandate for lower drug costs by governments and private payers. A biosimilar is a biologic product that has been demonstrated to be highly similar to a biologic product that is already licensed, referred to as a reference product, notwithstanding minor differences in clinically inactive components, and where there are no clinically meaningful differences between the reference product and the biosimilar in terms of the safety, purity, and potency of the product. By 2020, 8 biologic products representing approximately $45.6 billion of aggregate 2015 product sales are expected to lose patent protection and become available globally for biosimilars according to IMS Health.

The market opportunities for our most advanced product candidates are substantial. Lucentis achieved approximately $3.6 billion in global product sales in 2015. By the second quarter of 2018, markets with 2015 Lucentis sales of approximately $530 million are expected to lose patent protection, and become available to biosimilars. Additionally, by the second quarter of 2020, markets with an additional $1.8 billion in 2015 Lucentis sales are expected to lose patent protection and become available for biosimilars, and after January 2022 markets

with an additional $1.2 billion in 2015 sales are expected to also lose patent protection. Approximately $70 million in 2015 Lucentis sales come from markets for which accurate patent expiration dates are not available. Forteo achieved product sales of approximately $1.4 billion in 2015. Almost half of these product sales came from the US alone, followed by Japan. Forteo is expected to lose patent protection in the US, EU and Japan in 2019.

Our revenue for the years ended December 31, 2016, 2015, and 2014 was $60.2 million, $9.6 million, and $10.6 million, respectively. As a result of the termination of the development and license agreement with Pfizer in August 2016, $45.8 million of revenue was recognized that had been previously deferred. Our historical revenue has been primarily derived from monetizing our P*f*ēnex Expression Technology® through collaboration agreements, service agreements, government contracts and reagent protein product sales, which provide for various types of payments, including upfront payments, funding of research and development, milestone payments, intellectual property access fees and licensing fees. Currently, various government agencies are funding costs associated with our proprietary novel vaccine programs. As we continue to focus our business on the development of our product pipeline, we anticipate allocating fewer resources to certain aspects of our protein production activities that currently generate our revenue, which we expect will result in a decline of service-related revenue associated with protein production.

As of December 31, 2016, we had an accumulated deficit of $136.0 million of which $89.8 million was attributable to recognizing the accretion in the redemption value of our convertible preferred stock. We recognized net income of $5.5 million for the year ended December 31, 2016 and net losses of $28.2 million and $9.8 million for the years ended December 31, 2015 and 2014, respectively. We expect to incur substantial and increasing losses for the next several years as we develop and advance our lead product candidates through clinical development, expand our research and development activities, and prepare for the potential commercial launch of our lead product candidates. As a result, our research and development expenses will increase materially as we incur further costs of development. We currently utilize third-party clinical research organizations, or CROs, to carry out our clinical development and we do not yet have an extensive sales organization. We will need substantial additional funding to support our operating activities, especially as we approach anticipated regulatory approval in the United States, Europe and other territories, and begin to establish our commercialization capabilities. Adequate funding may not be available to us on commercially reasonable terms, or at all. Since our inception, we have funded our operations primarily through the sale and issuance of common stock in our public offerings, revenue from our collaboration agreements, government contracts, service agreements, and reagent protein product sales, our prior credit facility and the private placement of equity securities. We have devoted substantially all of our capital resources to the research and development of our product candidates and working capital requirements. Additionally, as we continue to focus our business on the development of our product pipeline, we anticipate allocating fewer resources to certain aspects of our protein production activities that currently generate our revenue, which we expect will result in a decline of service-related revenue.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. Historical results are not necessarily indicative of future results.

We believe the following critical accounting policies involve significant judgements and estimates used in the preparation of our consolidated financial statements (see also Note 1 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K).

Revenues

In accordance with GAAP, we recognize revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

We consider a variety of factors in determining the appropriate method of accounting for our licensing and collaboration agreements, including whether multiple deliverables can be separated and accounted for individually as separate units of accounting. Where there are multiple deliverables within a collaboration agreement that cannot be separated and therefore are combined into a single unit of accounting, revenues are deferred and recognized over the estimated period of performance. If the deliverables can be separated, we apply the relevant revenue recognition guidance to each individual deliverable. The specific methodology for the recognition of the underlying revenue is determined on a case-by-case basis according to the facts and circumstances applicable to each agreement.

Upfront, nonrefundable licensing payments are assessed to determine whether or not the licensee is able to obtain standalone value from the license apart from the other deliverables in the arrangement. Where the license does not have standalone value, non-refundable license fees are recorded as deferred revenue and recognized as revenue as we perform under the applicable agreement. Where the level of effort is relatively consistent over the performance period, we recognize fixed or determinable revenue on a straight-line basis over the estimated period of performance. Where the license has standalone value, we recognize total license revenue at the time all revenue recognition criteria have been met.

Nonrefundable payments for research funding are recognized as revenue over the period the underlying research activities are performed.

Revenues under service agreements are recorded as services are performed. These agreements do not require scientific achievement as a performance obligation and provide for payment when services are rendered. All such revenue is nonrefundable. Upfront, nonrefundable payments for license fees, exclusivity and services received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract term or period of performance based on the nature of the related agreement.

Revenue for our cost plus fixed fee government contracts is recognized in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contractors. Reimbursable costs under our government contracts primarily include direct labor, materials, subcontracts, accountable property and indirect costs. In addition, we receive a fixed fee under our government contracts, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under our government contracts, including the fixed fee, are recognized as revenue in the period the reimbursable costs are incurred and become billable.

We assess milestone fees on an individual basis and recognize revenue from nonrefundable milestone fees when the earnings process is complete and the payment is reasonably assured. Nonrefundable milestone fees related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the associated milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the milestone event.

Cost of Revenues

Cost of revenues includes costs incurred in connection with the execution of service contracts, government contracts, as well as costs to manufacture or purchase, package and ship our reagent products. Cost of revenues also includes development costs for our proprietary novel vaccine programs which are funded by various government agencies.

Research and Development Expenses

Research and development expenses are recognized as incurred. We expect our research and development expenses to increase for the foreseeable future as we advance our product candidates through our clinical development programs.

Preclinical and Clinical Trial Accruals

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf.

We estimate preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation

We generally grant equity-based awards under our share-based equity incentive plans and employee stock purchase plan. We have granted, and may in the future grant, options and restricted stock awards to employees, directors, consultants and advisors under our 2014 and 2016 equity incentive plans and our employee stock purchase plan (“ESPP”).

As of December 31, 2016, there were no shares available for issuance under the 2009 Plan, 0.6 million shares available for issuance under the 2014 Plan, 0.3 million shares available for issuance under the 2016 Plan, and 1.0 million shares available for issuance under the ESPP.

Employee stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense, net of estimated forfeitures, over the requisite service period. Stock-based compensation expense is amortized on a straight-line basis over the requisite service period for the entire award, which is the vesting period of the award.

We estimate the fair value of stock options and other equity-based compensation using a Black Scholes option pricing model on the date of grant. The Black-Scholes valuation model requires multiple subjective inputs. The fair value of equity instruments expected to vest are recognized and amortized on a straight line basis over the requisite service period of the award, which is generally four years; however, certain provisions in our equity compensation plan provide for shorter and longer vesting periods under certain circumstances.

See Note 11 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information concerning certain of the specific assumptions used in applying the Black-Scholes option pricing model to determine the estimated fair value of employee stock options granted in 2016, 2015 and 2014.

The Black-Scholes option pricing model requires the input of highly subjective assumptions, including the risk-free interest rate, the expected dividend yield of our common stock, the expected volatility of the price of our common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Other Information

Income Tax Matters

We file U.S. federal income tax returns and California and Massachusetts state tax returns. We are also subject to income tax in India. To date, we have not been audited by the Internal Revenue Service or any state tax authority; however, tax years from and including 2012 remain open for examination by federal and state income tax authorities. We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future tax benefit, if any, to be derived from tax credits and loss carryforwards. Deferred income tax expense or benefit would represent the net change during the year in the deferred income tax asset or liability. Deferred tax assets, if any, are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

During the years ended December 31, 2016 and 2015, we recorded an income tax benefit of $0.2 million and an income tax provision of $0.5 million, respectively, which is principally attributable to U.S. federal and state income taxes. No income tax provision was recorded during the year ended December 31, 2014. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties on our consolidated balance sheets at December 31, 2016, 2015 and 2014.

As of December 31, 2016, we had federal and state research and development credits carryforwards of approximately $2.7 million and $1.7 million, respectively, to offset potential tax liabilities. The federal research and development credits have a 20-year carryforward period and being to expire in 2030 unless utilized. California research and development tax credits have no expiration. We have $19.9 million federal net operating loss carryforwards and $11.8 million of state net operating loss carryforwards as of December 31, 2016. The federal and state net operating losses can be carried forward until 2036 unless utilized.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of our net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. We have completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards and found that a greater than 50% cumulative change in ownership occurred in August of 2014 in conjunction with our initial public offering. We had significant built-in gains; therefore, all the pre-change net operating losses were available for utilization.

Results of Operations

Comparison of the years ended December 31, 2016, 2015 and 2014

The following table summarizes our net income (loss) during the periods indicated.

	Years Ended December 31,			% change from 2015 to 2016	% change from 2014 to 2015
	2016	2015	2014		
		(in thousands)			
Revenues	$60,194	$ 9,583	$10,644	528%	(10)%
Cost of revenues	5,313	4,640	7,233	15%	(36)%
Gross profit	54,881	4,943	3,411	1010%	45%
Operating expenses					
Selling, general and administrative	17,340	14,598	9,003	19%	62%
Research and development	32,418	18,183	4,125	78%	341%
Total operating expense	49,758	32,781	13,128	52%	150%
Income (loss) from operations	5,123	(27,838)	(9,717)	118%	186%
Other income (expense)	149	74	(77)	101%	196%
Net income (loss) before income taxes	5,272	(27,764)	(9,794)	119%	183%
Income tax (expense) benefit	209	(452)	—	146%	(100)%
Net income (loss)	$ 5,481	$(28,216)	$ (9,794)	119%	188%

Revenues

Revenue increased by $50.6 million, or 528%, from $9.6 million in 2015 to $60.2 million in 2016. The increase in revenue was primarily due to the termination of our development and license agreement with Pfizer. As a result of the termination in August 2016, the estimated performance period was accelerated resulting in the recognition of $45.8 million of revenue that had been previously deferred. As a result of the termination, we will not recognize any additional future revenue under the Pfizer development and license agreement. In addition, we recognized revenue of $4.9 million attributable to amortization of a development and license fee. We had a net increase in revenue of $0.9 million attributable to our Px563L product candidate under our government contracts, as the project moved into clinical trials in 2016, as well as a $0.6 million reduction in protein services revenue. We expect revenue related to our protein production services to decline in the near-term as we shift our resources to developing our product pipeline.

Revenue decreased by $1.0 million, or 10%, from $10.6 million in 2014 to $9.6 million in 2015. The change in revenue was primarily due to a $2.9 million net decrease attributable to our Px563L product candidate under our government contracts, as the development phase was completed and manufacturing activity commenced late in 2015, as well as a $0.9 million reduction in protein services revenue, offset by $3.0 million in revenue recognized attributed to the portion of the $51 million upfront payment under our agreement with Pfizer.

Cost of Revenues

Cost of revenue increased by $0.7 million, or 15%, to $5.3 million in 2016 compared to $4.6 million in 2015. The change was due primarily to a net increase of $0.7 million in costs for our proprietary novel vaccine program Px563L, which is funded by a government agency. Given the nature of the novel vaccine development process, these costs will fluctuate depending on stage of development.

Cost of revenue decreased by $2.6 million, or 36%, to $4.6 million in 2015 compared to $7.2 million in 2014. This change was due primarily to a net decrease of $2.0 million in costs for our proprietary novel vaccine program Px563L which is funded by a government agency, as development was completed and the

manufacturing phase began in late 2015, as well as decreased costs of $0.2 million attributable to reduced activity related to our Px533 product candidate and a $0.1 million decrease due to reduced activity in protein services work.

Selling, General and Administrative

Selling, general and administrative expenses increased by $2.7 million, or 19% to $17.3 million in 2016 compared to $14.6 million in 2015. The increase in selling, general and administrative was primarily due to higher personnel-related expenses.

Selling, general and administrative expenses increased by $5.6 million, or 62% to $14.6 million in 2015 compared to $9.0 million in 2014. The increase in selling, general and administrative was primarily due to hiring for compliance for public markets and an increase in activities associated with operating as a publicly-traded company.

We expect general and administrative costs to continue to increase for activities associated with company operations. These increases will likely include the hiring of additional personnel. In addition, we intend to continue to incur increased internal and external business development costs to support our various product development efforts, which can vary from period to period.

Research and Development

Research and development expenses increased by approximately $14.2 million, or 78%, to $32.4 million in 2016 compared to $18.2 million in 2015. The increase in research and development expenses was due to manufacturing and development activities of PF708, which is being developed as a therapeutically equivalent candidate Forteo, and our other biosimilar product candidates. The bioequivalence study for PF708 was completed in 2016 and additional expenses were incurred to support upcoming clinical trials and US regulatory submissions.

Research and development expenses increased by approximately $14.1 million, or 341%, to $18.2 million in 2015 compared to $4.1 million in 2014. The increase in research and development expenses was due primarily to manufacturing and development activities to support upcoming clinical studies and US regulatory submissions, as well as initiation of process development, offset by a decrease due to the Pfizer collaboration on PF582.

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf.

We estimate preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered.

We expect research and development expenses to increase as we advance our lead candidates and pipeline product candidates. The funding necessary to bring a drug candidate to market is subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding

constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization.

Liquidity and Capital Resources

The following table summarizes our cash, cash equivalents and short term investments for the periods indicated:

	December 31,	
	2016	2015
	(in thousands)	
Cash, cash equivalents and short-term investments	$81,501	$106,162

To date, we have funded our operations primarily through the sale and issuance of common stock in our public offerings, revenue from our collaboration agreements, government contracts, service agreements, and reagent protein product sales, our prior credit facility and the private placement of equity securities. At December 31, 2016, we had $81.5 million in cash, cash equivalents and short-term investments compared to $106.2 million as of December 31, 2015 and $4.0 million in restricted cash as collateral for lines of credit at December 31, 2015. As of December 31, 2015, we had $3.8 million drawn under our prior $3.9 million Amended Credit Facility. In February 2016, we terminated the credit facility and repaid the amount outstanding using our restricted cash.

In July 2016, we entered into an agreement with Jazz to develop certain hematology products. Under the terms of the collaboration, we received upfront and option payments totaling $15 million in July 2016, and may be eligible to receive additional payments of up to $166 million based on the achievement of certain development, regulatory, and sales-related milestones, including up to $41 million for certain non-sales-related milestones. We may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration.

In August 2016, following Pfizer's strategic review of the current therapeutic focus of its biosimilar pipeline, our development and license agreement with Pfizer was terminated and all rights to PF582 were returned to us. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred. As a result of the termination of the development and license agreement with Pfizer, management is assessing all opportunities for the continued advancement of PF582, and we may need to obtain substantial additional sources of funding to develop PF582 as currently contemplated. If such additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our PF582 development program, or grant rights in the United States, as well as outside the United States, to PF582 to one or more partners.

We believe that our existing cash and cash equivalents and our cash inflow from operations will be sufficient to meet our anticipated cash needs for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital although we may receive milestone and other contingent payments under our current license and collaboration agreements. Our future capital requirements will depend on many factors, including:

- the timing and extent of spending on our research and development efforts, including with respect to PF708 and PF582, and our other product candidates;
- our ability to enter into and maintain collaboration, licensing, commercialization and other arrangements and the terms and timing of such arrangements;

- the cost of manufacturing and commercialization activities, if any;
- the receipt of any collaboration or milestone payments;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the emergence of competing technologies or other adverse market developments;
- the time and costs involved in seeking and obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the degree and rate of market acceptance of any products launched by us or our collaboration partners;
- the expansion of our sales and marketing activities; and
- the potential acquisition and in-licensing of other technologies, products or assets.

We will need to raise additional capital to fund our operations in the near future. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below.

	Years Ended December 31,		
	2016	**2015**	**2014**
		(in thousands)	
Net cash (used in) provided by:			
Operating activities	$ (22,274)	$ 24,230	$ (10,002)
Investing activities	(2,860)	(1,470)	934
Financing activities	473	37,680	50,836
Net increase (decrease) in cash and cash equivalents	$ (24,661)	$ 60,440	$ 41,768

Net cash used in operating activities was $22.3 million for the year ended December 31, 2016 compared to net cash provided of $24.2 million for the year ended December 31, 2015. Net cash used in operating activities in

2016 was primarily attributable to our research and development activities associated with PF708 and our other product candidates, partially offset by $15 million of upfront and option payments received pursuant to our license and option agreement with Jazz. In addition, our general and administrative costs increased due to higher headcount and marketing and legal expenses. We anticipate using cash in operating activities for our research and development efforts for the foreseeable future.

Net cash provided by operating activities was $24.2 million for the year ended December 31, 2015 compared to net cash used of $10.0 million for the year ended December 31, 2014. Cash was provided mainly by the $51.0 million received from Pfizer in March 2015. This was offset by net losses associated with our research and development activities. In addition, we increased our general and administrative costs as a result of activities associated with operating as a publicly-traded company.

Net cash used in investing activities was $2.9 million for the year ended December 31, 2016 compared to net cash used of $1.5 million for the year ended December 31, 2015. We used $2.9 million and $1.5 million in 2016 and 2015, respectively, to purchase property and equipment.

Net cash used in investing activities was $1.5 million for the year ended December 31, 2015 compared to net cash provided of $0.9 million for the year ended December 31, 2014. We had no maturities of short-term investments in 2015 and $1.3 million in maturities of short-term investments in 2014. We used $1.5 million and $0.3 million in 2015 and 2014, respectively, to purchase property and equipment.

Net cash provided by financing activities was $0.5 million for the year ended December 31, 2016 compared to net cash provided of $37.7 million for the year ended December 31, 2015. Net cash provided by financing activities in 2016 resulted primarily from the issuance of common stock in connection with our Employee Stock Purchase Plan and exercises of stock options and a refund of the residual restricted cash resulting from the $3.8 million repayment of the Amended Credit Facility upon termination in February 2016. Net cash provided by financing activities in 2015 was primarily related to the net proceeds of $37.3 million from the issuance of our common stock in connection with our follow-on offering after deducting estimated offering expenses of approximately $0.7 million.

Net cash provided by financing activities was $37.7 million for the year ended December 31, 2015 compared to net cash provided of $50.8 million for the year ended December 31, 2014. In 2015, we received net proceeds of approximately $37.3 million from the issuance of our common stock in connection with our follow-on offering after deducting offering expenses. In 2014, we received net proceeds of approximately $50.6 million, from the issuance of our common stock in connection with our IPO after deducting offering expenses. We did not draw down on our prior revolving credit in 2015, but borrowed approximately $0.2 million in 2014. We received $0.3 million and $0.1 million in 2015 and 2014, respectively, for the issuance of common stock in connection with exercises of stock options.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K, other than a joint venture agreement, or JVA, with Strides Arcolab, and the agreements containing indemnification provisions described below.

In March 2013, we and Strides Arcolab entered into the JVA. The JVA was established to provide a vehicle for the advancement of certain biosimilars successful in Phase 1 trials under a joint development and license agreement between us and Strides Arcolab. Under the terms of the JVA, both parties share equally in all decisions, and share revenue and expenses at a rate of 51% to Strides Arcolab and 49% to us. There has been no activity in the joint venture, or JV, to date. Once a biosimilar product successfully completes a Phase 1 trial and Strides Arcolab and we agree to contribute the biosimilar to the JV, the JV will incur activity.

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification, including our Strides Arcolab agreements described above. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. As of December 31, 2016, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

Contractual Obligations and Commitments

The following summarizes our contractual obligations and commitments as of December 31, 2016:

	Payments due by period				
Contractual Obligations (*in thousands*)	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Capital lease obligations	$ 100	$ 60	$ 26	$ 14	$ —
Purchase obligations	15,807	15,320	487	—	—
Operating lease obligations	6,974	1,188	1,847	1,799	2,140
	$22,881	$16,568	$2,360	$1,813	$2,140

Purchase obligations represent agreements with contract research organizations and subcontractors to further develop our products. These contracts can be cancelled at any time, with some having certain cancellation fees associated with the termination of the contract, and others that only obligate us through the termination date.

In June 2010, we entered into a lease agreement (the Lease) with a landlord for an initial term of 10 years, for our corporate headquarters comprised of one building located in San Diego, California. Occupation of the premises under the Lease began in April 2011. Under the terms of the Lease, we pay annual base rent, subject to an annual fixed percentage increase, plus our share of common operating expenses. The annual base rent was subject to abatement of 50% for the first year of the lease. We recognize rent expense on a straight-line basis over the term of the Lease. The total estimated rent payments over the life of the Lease was $3.6 million.

In September 2014, we amended the Lease to extend the term for an additional three years through June 30, 2024 and to lease additional facilities consisting of 7,315 square feet, resulting in a total increase in the estimated rent payments over the life of the Lease by approximately $2.9 million. Base rent payments for the new space commenced in December 2014 and increased total estimated rent payments over the life of the Lease by approximately $1.5 million. The extended term on the existing space increased total estimated rent payments by approximately $1.4 million. In addition to the base rent, we are obligated to pay certain customary amounts for our share of operating expenses and tax obligations. In November 2015, we amended the Lease to add facilities consisting of 16,811 square feet. Base rent payments for a portion of the new space commenced in March 2016, which will increase total estimated rent payments over the life of the lease by approximately $2.3 million.

In March 2016, we entered into an operating lease for lab equipment with estimated total payments of $0.7 million over the two-year term.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09 Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to

obtain or fulfill a contract. Numerous updates were issued in 2016 that provide clarification on a number of specific issues as well as requiring additional disclosures. The effective date will be the first quarter of fiscal year 2019 using one of two retrospective application methods. We are in the process of determining the timing of adoption and the adoption method. We do not expect the new standard to have a material impact on the recognition of revenue from our reagent protein product sales. However, we continue to evaluate the impact that this guidance will have on our consolidated financial statements in connection with the contracts with BARDA and NIAID and our collaboration and license agreements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern. The provisions of ASU 2014-15 provide that, in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. ASU 2014-15 is effective for the annual reporting period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. We have adopted ASU No. 2014-15 for the year ended December 31, 2016 and the adoption did not have a material effect on our financial statement disclosures.

In February 2016, the FASB issued ASU No. 2016-02 Leases (Topic 842), which requires lessees to recognize "right of use" assets and liabilities for all leases with lease terms of more than 12 months. The ASU requires additional quantitative and qualitative financial statement footnote disclosures about the leases, significant judgments made in accounting for those leases and amounts recognized in the financial statements about those leases. The effective date will be the first quarter of fiscal year 2020. We are currently evaluating the impact of the adoption of this accounting standard update on our financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires, among other elements, the excess tax benefits and deficiencies related to employee share-based payment awards and related dividends to be recorded in the statement of operations during the reporting period in which they occur. Additionally, it allows us to make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest (consistent with current GAAP) or account for forfeitures when they occur. ASU 2016-09 also requires that all tax-related cash flows resulting from share-based payments, including the excess tax benefits related to the settlement of stock-based awards, be classified as cash flows from operating activities, and that cash paid by directly withholding shares for tax withholding purposes be classified as a financing activity in the Consolidated Statements of Cash Flows. We have elected to early adopt ASU 2016-09 in the fourth quarter of fiscal 2016. Amendments requiring recognition of excess tax benefits and tax deficiencies within the Consolidated Statements of Operations were adopted prospectively and resulted in the recognition of no excess tax benefits within income tax (benefit) expense, as any impact is offset by a change in valuation allowance. We have elected to continue to estimate forfeitures expected to occur to determine the amount of compensation expense to be recognized in each period. ASU 2016-09 amendments related to presentation within the Consolidated Statements of Cash Flows were applied prospectively and resulted in no reclassification of excess tax benefits related to the settlement of stock-based awards from financing to operating activities, and no taxes paid related to net share settlements of stock-based compensation awards from operating activities to financing activities for the year ended December 31, 2016.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which clarifies the presentation of restricted cash and restricted cash equivalents in the statements of cash flows. Under the ASU, restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts presented on the statements of cash flows. The ASU is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the Consolidated Statement of Cash Flows. The ASU requires that the Consolidated Statement of Cash Flows explain the change in total cash and equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The ASU

also requires a reconciliation between the total of cash and equivalents and restricted cash presented on the Consolidated Statement of Cash Flows and the cash and equivalents balance presented on the Consolidated Balance Sheet. The ASU is effective retrospectively on January 1, 2018, with early adoption permitted. We do not expect the adoption of the ASU to have a material effect on its results of operations, financial condition or cash flows.

Segment Information

We operate in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. During 2016, substantially all of our long-lived assets were located within the United States. With the exception of $0.1 million of long-lived assets held by a third-party vendor in India for manufacturing purposes, during 2015 all of our long-lived assets were located within the United States. During 2014, all of our long-lived assets were located within the United States.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and foreign currency exchange rates. As of December 31, 2016, we did not hold or issue financial instruments for trading purposes.

Interest rate fluctuation risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds, treasury obligations, short term certificates of deposit and high-grade corporate securities, directly or through managed funds, with maturities of six months or less. As of December 31, 2016, we had cash and cash equivalents of $81.5 million consisting of cash of $4.5 million and investments of $77.0 million in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 100 basis point movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Foreign currency exchange risk

We contract with clinical research organizations, investigational sites and suppliers in foreign countries. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We have not entered into any material foreign currency hedging contracts although we may do so in the future. To date we have not incurred any material effects from foreign currency changes on these contracts. The effect of a 10% adverse change in exchange rates on foreign currency denominated cash and payables as of December 31, 2016 would not have been material. However, fluctuations in currency exchange rates could harm our business in the future.

Inflation risk

Inflation may affect us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations for any period presented herein.

Item 8. ***Financial Statements and Supplementary Data***

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Pfenex Inc.:

We have audited the accompanying consolidated balance sheet of Pfenex Inc. and subsidiary as of December 31, 2016, and the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year ended December 31, 2016. In connection with our audit of the consolidated financial statements, we have also audited the financial statement schedule II for the year ended December 31, 2016. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pfenex Inc. and subsidiary as of December 31, 2016, and the results of their operations and their cash flows for the year ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule II for the year ended December 31, 2016, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Diego, California
March 15, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Pfenex Inc.
San Diego, California

We have audited the accompanying consolidated balance sheet of Pfenex Inc. (the "Company") as of December 31, 2015, and the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the years ended December 31, 2015 and 2014. In connection with our audits of the consolidated financial statements, we have also audited the financial statement schedule for each of the years ended December 31, 2015 and 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pfenex Inc. as of December 31, 2015, and the consolidated results of its operations and its cash flows for each of the years ended December 31, 2015 and 2014 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule for each of the years ended December 31, 2015 and 2014, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ HASKELL & WHITE LLP

HASKELL & WHITE LLP

San Diego, California
March 10, 2016

PFENEX INC.

Consolidated Balance Sheets

	December 31,	
	2016	**2015**
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 81,501	$ 106,162
Restricted cash	—	3,959
Accounts and unbilled receivables, net	2,822	2,683
Income tax receivable	717	508
Other current assets	1,878	1,718
Total current assets	86,918	115,030
Deferred income taxes	—	1,955
Property and equipment, net	5,246	3,179
Other long term assets	80	121
Intangible assets, net	5,301	5,832
Goodwill	5,577	5,577
Total assets	$ 103,122	$ 131,694
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,284	$ 886
Accrued liabilities	9,412	5,997
Current portion of deferred revenue	6,516	3,870
Line of credit obligation	—	3,813
Income tax payable	—	1,676
Total current liabilities	17,212	16,242
Deferred revenue, less current portion	5,739	44,225
Other long-term liabilities	26	46
Total liabilities	22,977	60,513
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding		
Common stock, par value $0.001, 200,000,000 shares authorized at December 31, 2016 and 2015, respectively, 23,429,501 and 23,316,413 shares issued and outstanding at December 31, 2016 and 2015, respectively	24	24
Additional paid-in capital	216,144	212,661
Accumulated deficit	(136,023)	(141,504)
Total stockholders' equity	80,145	71,181
Total liabilities and stockholders' equity	$ 103,122	$ 131,694

The accompanying notes are an integral part of these consolidated financial statements.

PFENEX INC.

Consolidated Statements of Operations

	Years Ended December 31,		
	2016	**2015**	**2014**
	(in thousands except for per share data)		
Revenues	$60,194	$ 9,583	$10,644
Cost of revenues	5,313	4,640	7,233
Gross profit	54,881	4,943	3,411
Operating expense			
Selling, general and administrative	17,340	14,598	9,003
Research and development	32,418	18,183	4,125
Total operating expense	49,758	32,781	13,128
Income (loss) from operations	5,123	(27,838)	(9,717)
Other income (expense), net	149	74	(77)
Net income (loss) before income taxes	5,272	(27,764)	(9,794)
Income tax benefit (expense)	209	(452)	—
Net income (loss)	$ 5,481	$(28,216)	$ (9,794)
Net income (loss) per common share basic	$ 0.23	$ (1.26)	$ (1.04)
Net income (loss) per common share diluted	$ 0.23	$ (1.26)	$ (1.04)
Weighted-average common shares used to compute basic net income (loss) per share	23,389	22,376	9,441
Weighted-average common shares used to compute diluted net income (loss) per share	23,688	22,376	9,441

The accompanying notes are an integral part of these consolidated financial statements

PFENEX INC.

Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands)

	Redeemable Convertible A-2 Preferred Stock		Redeemable Convertible A-1 Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Earnings (Deficit)	Total Stockholders' Equity/ (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2014	3,556	$ 49,200	4,979	$ 63,980	1,542	$ 2	$ —	$ (94,453)	$ (94,451)
Exercise of stock options	—	—	—	—	104	1	55	—	56
Stock-based compensation expense	—	—	—	—	—	—	404	—	404
Accretion of redemption value	—	200	—	560	—	—	(93)	(667)	(760)
Preferred stock dividends paid in common shares	—	—	—	—	1,218	1	7,306	(7,307)	—
Conversion of preferred stock to common stock	(3,556)	(49,400)	(4,979)	(64,540)	8,635	9	113,931	—	113,940
Issuance of common stock, net of discount	—	—	—	—	9,429	9	52,605	—	52,614
Repurchase of common stock	—	—	—	—	(423)	(1)	(130)	—	(131)
Offering costs	—	—	—	—	—	—	(2,003)	—	(2,003)
Common stock forfeiture	—	—	—	—	(100)	—	(1)	—	(1)
Beneficial dividend	—	—	—	—	—	—	1,067	(1,067)	—
Net loss	—	—	—	—	—	—	—	(9,794)	(9,794)
Balance at December 31, 2014	—	$ —	—	$ —	20,405	$ 21	$173,141	$(113,288)	$ 59,874
Exercise of stock options	—	—	—	—	277	—	201	—	201
Issuance of common stock under employee stock purchase plan	—	—	—	—	24	—	140	—	140
Stock-based compensation expense	—	—	—	—	—	—	1,840	—	1,840
Issuance of common stock, net of discount	—	—	—	—	2,610	3	38,025	—	38,028
Offering costs	—	—	—	—	—	—	(686)	—	(686)
Net loss	—	—	—	—	—	—	—	(28,216)	(28,216)
Balance at December 31, 2015	—	$ —	—	$ —	23,316	$ 24	$212,661	$(141,504)	$ 71,181
Exercise of stock options	—	—	—	—	78	—	123	—	123
Issuance of common stock under employee stock purchase plan	—	—	—	—	36	—	204	—	204
Stock-based compensation expense	—	—	—	—	—	—	3,156	—	3,156
Net income	—	—	—	—	—	—	—	5,481	5,481
Balance at December 31, 2016	—	$ —	—	$ —	23,430	$ 24	$216,144	$(136,023)	$ 80,145

The accompanying notes are an integral part of these consolidated financial statements

PFENEX INC.

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2016	2015	2014
		(in thousands)	
Cash flows from operating activities			
Net income (loss)	$ 5,481	$ (28,216)	$ (9,794)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Depreciation and amortization	670	541	465
Amortization of intangible assets	531	531	529
Deferred income taxes	1,955	(1,955)	—
Stock-based compensation expense	3,156	1,840	404
Loss on disposal of property and equipment	250	59	—
Changes in operating assets and liabilities			
Accounts and unbilled receivables	(139)	(1,099)	1,877
Other current assets	(160)	58	(1,466)
Notes receivable from related parties	—	—	95
Other long term assets	25	(68)	(17)
Accounts payable	431	(243)	(675)
Accrued liabilities	3,250	3,318	(365)
Deferred revenue	(35,840)	47,894	(1,051)
Income tax (receivable) payable	(1,884)	1,570	(4)
Net cash provided by (used in) operating activities	(22,274)	24,230	(10,002)
Cash flows from investing activities			
Sales/maturities of investments	—	—	1,250
Acquisitions of property and equipment	(2,868)	(1,470)	(316)
Proceeds from sales of equipment	8	—	—
Net cash provided by (used in) investing activities	(2,860)	(1,470)	934
Cash flows from financing activities			
Borrowings under line of credit agreement	—	—	223
Repayments of borrowings under line of credit agreement	(3,813)	—	—
Restricted cash	3,959	(4)	74
Repurchase of common stock	—	—	(131)
Proceeds from exercise of stock options and other stock issuances	327	342	56
Proceeds from issuance of common shares from initial public offering	—	—	50,614
Proceeds from issuance of common shares from secondary offering	—	37,342	—
Net cash provided by financing activities	473	37,680	50,836
Net increase (decrease) in cash and cash equivalents	(24,661)	60,440	41,768
Cash and cash equivalents			
Beginning of year	106,162	45,722	3,954
End of year	$ 81,501	$106,162	$ 45,722
Supplemental schedule of cash flow information			
Cash paid for interest	$ 30	$ 104	$ 91
Cash paid for taxes	$ 32	$ 942	$ 25
Non-cash financing and investing transactions			
Conversion of preferred stock to common stock	$ —	$ —	$113,940
Preferred stock dividends paid in common shares	$ —	$ —	$ 7,307
Beneficial dividend	$ —	$ —	$ 1,067
Reclass from permanent to temporary equity and accretion of preferred stock redemption value	$ —	$ —	$ 760
Capital lease obligation	$ 42	$ 89	$ 130
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 248	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements

PFENEX INC.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Business Activities and Organization

Pfenex Inc. ("Company" or "Pfenex") was incorporated in the state of Delaware in 2009. Pfenex is a clinical-stage biotechnology company engaged in the development of biosimilar and therapeutic equivalents to branded therapeutics and other high-value and difficult to manufacture proteins. The Company's lead product candidates are PF708 and PF582. PF708 is a therapeutic equivalent candidate to Forteo (teriparatide), marketed by Eli Lilly and Company, for the treatment of osteoporosis. A bioequivalence study for PF708 was completed in the second quarter of 2016. The interim pharmacokinetic data from this study is expected in the second half of 2017 and the immunogenicity data is expected in the first half of 2018. PF582, a biosimilar to Lucentis (ranibizumab), is marketed by Genentech, Inc., a wholly-owned member of the Roche Group and Novartis AG, for the treatment of patients with retinal diseases. The Company completed a Phase 1/2 trial in patients with wet age-related macular degeneration, or wet AMD, with Hospira, Inc. ("Hospira"), a subsidiary of Pfizer Inc. (collectively with Hospira, "Pfizer"). Pfenex regained full rights to PF582 following Pfizer's strategic review of the therapeutic focus of its biosimilars pipeline. To that effect, in August 2016, the Company and Pfizer entered into a termination agreement, pursuant to which the development and license agreement was terminated and all rights to PF582 were returned to the Company. The termination accelerated recognition of $45.8 million of revenue that had been previously deferred. The Company also announced top-line results from the Phase 1/2 trial, which showed that PF582 was pharmacologically active and with a safety profile that was consistent with that of Lucentis. In addition to the Company's two lead product candidates, its pipeline includes various other biosimilar candidates as well as vaccines and next generation biologic candidates. The Company initiated a Phase 1a study for its recombinant anthrax vaccine at the end of 2015 and announced interim Day 70 results in the third quarter of 2016.

The Company's revenue in the near term is primarily related to monetizing its protein production platform through collaboration agreements, service agreements, government contracts and reagent protein product sales which may provide for various types of payments, including upfront payments, funding of research and development, milestone payments, intellectual property access fees and licensing fees.

Reverse Stock Split

On June 27, 2014, the Company effected a 2.812-for-1 reverse stock split of its common and preferred stock. All share and per share information has been retroactively adjusted to reflect this reverse stock split.

Initial Public Offering

In July 2014, the Company completed its initial public offering ("IPO") in which 8,333,333 shares of common stock at a price of $6.00 per share were issued and sold. Additionally, the Company sold 1,095,751 shares of common stock pursuant to the underwriters' option to purchase additional shares. The Company received aggregate proceeds of approximately $52.6 million from the sale of shares of common stock, net of underwriters' discounts and commissions, but before deducting paid and unpaid offering expenses of approximately $2.0 million. In connection with the IPO, (i) all shares of the Company's outstanding convertible preferred stock automatically converted into 8,634,857 shares of common stock; (ii) the Company issued 1,217,784 shares of common stock as payment of all accrued and unpaid dividends through July 28, 2014; (iii) the Company repurchased 423,185 shares of its common stock at a purchase price of $0.31 per share pursuant to the amended and restated subscription agreement, dated May 2, 2014, entered into with certain stockholders, including Signet Healthcare Partners Accredited Partnership III, LP and Signet Healthcare Partners QP Partnership III, LP; and (iv) certain members of the Company's executive management team forfeited an aggregate of 100,000 shares of common stock.

Follow-on Public Offering

In April 2015, the Company completed a follow-on public offering pursuant to which it sold 2,610,000 shares of its common stock at a price to the public of $15.50 per share. In addition, certain existing stockholders sold 4,140,000 shares of common stock in the underwritten public offering at the same per-share price. The total proceeds the Company received from the offering were approximately $38.0 million, net of underwriting discounts and commissions of approximately $2.4 million. After deducting estimated offering expenses of $0.7 million, net proceeds to the Company were $37.3 million.

Subsidiary—Pfenex India Development Private Limited ("Pfenex India")

In July 2016, to assist with the continued research and development of its pipeline products, the Company formed a new entity in India. An application for incorporation with the Government of India Ministry of Corporate Affairs was filed and approved for the Company's subsidiary, Pfenex India Development Private Limited. There has been limited activity in the subsidiary, consisting mainly of set-up costs, and all intercompany transactions have been eliminated in the consolidated financial statements.

Pfenex India uses its local currency, the India Rupee, as its functional currency, the local currency denominated assets and liabilities are translated at the period end exchange rates, and costs and expenses are translated at the period end exchange rates during the periods then ended. No gain or loss resulting from foreign currency translation is included as a component of accumulated other comprehensive income or loss because the impact was immaterial.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, all adjustments considered necessary for a fair presentation have been included. These adjustments consist of normal and recurring accruals, as well as non-recurring charges.

Certain immaterial reclassifications of 2015 amounts have been made to conform with the 2016 presentation.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. During 2016, substantially all of the Company's long-lived assets were located within the United States.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Estimates have been prepared on the basis of the most current and best available information. However, actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of three months or less at the time of purchase to be cash equivalents.

Restricted Cash

As discussed in Note 6, the Company had a line of credit with Wells Fargo Bank, National Association ("Wells Fargo") under which the Company could borrow up to $3.9 million. The line of credit was secured by a security interest of first priority in favor of Wells Fargo in all funds deposited into the Company's money market account held at Wells Fargo. In February 2016, the Company terminated the credit facility and repaid the amount outstanding using its restricted cash.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, investments and accounts and unbilled receivables. The Company has established guidelines intended to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio and placing investments with maturities that help maintain safety and liquidity. All cash and cash equivalents were held at four major financial institutions as of December 31, 2016 and three major financial institutions as of December 31, 2015. For the Company's cash position of $81.5 million as of December 31, 2016, the Company has exposure to credit loss for amounts in excess of insured limits in the event of non-performance by the institutions; however, the Company does not anticipate non-performance.

Additional credit risk is related to the Company's concentration of receivables. As of December 31, 2016, receivables were concentrated among three customers representing 89% of total net receivables and one customer as of December 31, 2015, representing 88%. The Company recognized $45.8 million in revenue upon termination of the Pfizer agreement in August 2016. Revenue from Pfizer represented 80% of total revenue for the year ended December 31, 2016. Two customers, including Pfizer, represented 70% of total revenue for the year ended December 31, 2015. For the year ended December 31, 2014, revenue was concentrated among three customers, representing 82% of total revenues. There were no supplier concentrations.

A portion of revenue is earned from sales outside the United States. Non-U.S. revenue is denominated in U.S. dollars. A breakdown of the Company's revenue from U.S. and non-U.S. sources for the years ended December 31, 2016, 2015 and 2014 is as follows:

	Years Ended December 31,		
	2016	2015	2014
		(in thousands)	
US Revenue	$54,641	$8,399	$ 8,782
Non-US Revenue	5,553	1,184	1,862
	$60,194	$9,583	$10,644

For the years ended December 31, 2016 and 2015, no single foreign country accounted for more than 10% of the Company's revenues. For the year ended December 31, 2014, Germany accounted for 10% of the Company's revenues.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals.

Products developed by the Company require clearances from international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed or the Company was unable to maintain clearance, it could have a materially adverse impact on the Company.

As of December 31, 2016, the Company had an accumulated deficit of $136.0 million and expects to incur substantial operating losses for the next several years. It will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

Accounts and Unbilled Receivables

Accounts receivable represent primarily commercial receivables associated with the Company's service fees, license fees, product sales and receivables from U.S. government contracts. Accounts receivable amounted to $1.9 million and $1.1 million as of December 31, 2016 and 2015, respectively. Unbilled receivables represent reimbursable costs in excess of billings and, where applicable, accrued profit related to long-term government contracts for which revenue has been recognized, but the customer has not yet been billed. Unbilled receivables amounted to $1.0 million and $2.0 million as of December 31, 2016 and 2015, respectively.

The Company evaluates the collectability of its receivables based on a variety of factors, including the length of time the receivables are past due, the financial health of its customers and historical experience. Based upon the review of these factors, the Company recorded an allowance for doubtful accounts of $0.1 million and $0.4 million at December 31, 2016 and 2015, respectively.

Fair Value of Financial Instruments

Financial instruments, including cash, cash equivalents, restricted cash and the lines of credit, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Observable inputs such as quoted prices in active markets for identical assets or liabilities. Level 1 assets at December 31, 2016 and December 31, 2015 included the Company's cash and cash equivalents. There were no Level 1 liabilities;
- Level 2—Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly. The Company had no Level 2 assets or liabilities at December 31, 2016 or December 31, 2015; and
- Level 3—Unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of assets or liabilities in which there is little or no market data. The Company had no Level 3 assets or liabilities at December 31, 2016 or December 31, 2015.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from five to ten years with the exception of leasehold improvements which are amortized over the shorter of the lease term or their estimated useful life.

Intangible Assets

Intangible assets include customer relationships, developed technology and trade names related to the Company's asset acquisition and have been capitalized and amortized over the estimated useful life of 15 years, 20 years and 15 years, respectively.

Impairment of Long-Lived Assets Other Than Goodwill

The Company assesses potential impairments to its long-lived assets whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flow expected to result from the use of the assets. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. No impairment was noted as of the years ended December 31, 2016 and 2015.

Goodwill

Goodwill is the excess of purchase price over the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed, in a business combination. The Company does not amortize goodwill. Instead, goodwill is tested for impairment annually and between annual tests if the Company becomes aware of an event or a change in circumstances that would indicate the carrying amount may be impaired. The Company performs its annual impairment testing as of December 31st of each year. The Company will first assess qualitative factors to determine whether the existence of events or circumstances suggests that it is more likely than not that goodwill is impaired. Unless it is more likely than not that goodwill is impaired, the Company does not perform the two-step impairment test. The Company's determination as to whether, and, if so, the extent to which, goodwill becomes impaired is highly judgmental and based on assumptions regarding its projected future operating results, changes in the manner of its use of the acquired assets or its overall business strategy and regulatory, market and economic environment and trends. No impairment was noted as of December 31, 2016 and 2015.

Revenue

The Company's revenue is related to the monetization of its protein production platform through collaboration agreements, service agreements, license agreements, government contracts and sales of reagent protein products which may provide for various types of payments, including upfront payments, funding of research and development, milestone payments, intellectual property access fees and licensing fees. The Company's revenue generating agreements also include potential revenues for achieving milestones and for product royalties. The specifics of the Company's significant agreements are detailed in Note 10—Significant Research and Development Agreements.

The Company considers a variety of factors in determining the appropriate method of accounting for its collaboration agreements, including whether multiple deliverables can be separated and accounted for individually as separate units of accounting. Where there are multiple deliverables within a collaboration agreement that cannot be separated and therefore are combined into a single unit of accounting, revenues are deferred and recognized using the relevant guidance over the estimated period of performance. If the deliverables can be separated, the Company applies the relevant revenue recognition guidance to each individual deliverable. The specific methodology for the recognition of the underlying revenue is determined on a case-by-case basis according to the facts and circumstances applicable to each agreement.

Upfront, nonrefundable licensing payments are assessed to determine whether or not the licensee is able to obtain standalone value from the license. Where the license does not have standalone value, non-refundable

license fees are recorded as deferred revenue and recognized as revenue as the Company performs under the applicable agreement. Where the level of effort is relatively consistent over the performance period, the Company recognizes fixed or determined revenue on a straight-line basis over the estimated period of performance. Where the license has standalone value, the Company recognizes total license revenue at the time all revenue recognition criteria have been met.

Nonrefundable payments for research funding are generally recognized as revenue over the period the underlying research activities are performed.

Revenue under service agreements are recorded as services are performed. These agreements do not require scientific achievement as a performance obligation and provide for payment when services are rendered. All such revenue is nonrefundable. Upfront, nonrefundable payments for license fees, exclusivity and feasibility services received in excess of amounts earned are classified as deferred revenue and recognized as income over the contract term or period of performance based on the nature of the related agreement.

The Company recognizes revenue for its cost plus fixed fee government contracts in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contractors. Reimbursable costs under the Company's government contracts primarily include direct labor, materials, subcontracts, accountable property and indirect costs. In addition, the Company receives a fixed fee under its government contracts, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under the Company's government contracts, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable.

The Company assesses milestone payments on an individual basis and recognizes revenue from nonrefundable milestone payments when the earnings process is complete and the payment is reasonably assured. Nonrefundable milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the associated milestone, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, and (ii) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the milestone event. The Company recognized $0.8 million in connection with the achievement of certain milestones under a development and license agreement for the year ended December 31, 2016. For the years ended December 31, 2015 and 2014, no revenue in connection with the achievement of milestones has been recognized.

The Company's reagent protein products are comprised of internally developed reagent protein products and those purchased from original manufacturers for resale. Revenues for reagent product sales are reflected net of attributable sales tax. The Company generally offers a 30 day return policy. The Company recognizes reagent product revenue from product sales when it is realized or realizable and earned. As of December 31, 2016, the Company has had minimal product returns related to reagent protein product sales. No reserve for warranty and return rights was recorded as of December 31, 2016, and reserves of $1 thousand and $10 thousand had been recorded as of December 31, 2015 and 2014, respectively. The reserve is a component of accounts and unbilled receivables, net in the accompanying consolidated balance sheets.

Revenue under arrangements where the Company outsources the cost of fulfillment to third parties is evaluated as to whether the related amounts should be recorded gross or net. The Company records amounts collected from the customer as revenue, and the amounts paid to suppliers as cost of revenue when it holds all or substantially all of the risks and benefits related to the product or service. For transactions where the Company does not hold all or substantially all the risk, the Company uses net reporting and therefore records the transaction as if the end-user made a purchase from the supplier with the Company acting as a sales agent.

Cost of Revenue

Cost of revenue includes costs incurred in connection with the execution of service contracts, as well as costs to manufacture or purchase, package and ship the Company's reagent products.

Preclinical and Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of series or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered.

Research and Development Expenses

Research and development expenses are recognized as incurred and amounted to $32.4 million, $18.2 million and $4.1 million for the years ending December 31, 2016, 2015 and 2014, respectively.

Stock-Based Compensation

Employee stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense, net of estimated forfeitures, over the requisite service period. Stock-based compensation expense is amortized on a straight-line basis over the requisite service period for the entire award, which is generally the vesting period of the award.

The Company estimates the fair value of stock options and other equity-based compensation using a Black-Scholes option pricing model on the date of grant. The Black-Scholes valuation model requires multiple subjective inputs, which are discussed further in Note 11 — Stock-Based Compensation. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally four years; however, certain provisions in the Company's equity compensation plan provides for shorter and longer vesting periods under certain circumstances.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Income Taxes

Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax

assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The Company accounts for interest and penalties related to income tax matters, if any, as a component of income tax expense or benefit.

Net Income (Loss) per Share of Common Stock

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding and potentially dilutive securities during the period under the treasury stock method. For purposes of the diluted net income (loss) per share calculation, stock options and employee purchase plan shares are considered to be potentially dilutive securities. Securities are excluded from the computation of diluted net income (loss) per share if their effect would be anti-dilutive to earnings per share. Because the Company has reported a net loss for the years ended December 31, 2015 and 2014, diluted net loss per common share is the same as basic net loss per common share for those periods. There were no accumulated dividends related to preferred stock at December 31, 2016, 2015 or 2014. Immediately prior to the IPO, the Company issued shares of common stock in connection with the payment of all accrued and unpaid dividends on the preferred stock upon the conversion of the convertible preferred stock to common stock. See Note 8—Common Stock and Preferred Stock.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09 Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Numerous updates were issued in 2016 that provide clarification on a number of specific issues as well as requiring additional disclosures. The effective date will be the first quarter of fiscal year 2019 using one of two retrospective application methods. The Company is in the process of determining the timing of adoption and the adoption method. It does not expect the new standard to have a material impact on the recognition of revenue from its reagent protein product sales. However, the Company continues to evaluate the impact that this guidance will have on its consolidated financial statements in connection with the contracts with BARDA and NIAID and its collaboration and license agreements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern. The provisions of ASU 2014-15 provide that, in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. ASU 2014-15 is effective for the annual reporting period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company has adopted ASU No. 2014-15 for the year ended December 31, 2016 and the adoption did not have a material effect on its financial statement disclosures.

In February 2016, the FASB issued ASU No. 2016-02 Leases (Topic 842), which requires lessees to recognize "right of use" assets and liabilities for all leases with lease terms of more than 12 months. The ASU

requires additional quantitative and qualitative financial statement footnote disclosures about the leases, significant judgments made in accounting for those leases and amounts recognized in the financial statements about those leases. The effective date will be the first quarter of fiscal year 2020. The Company is currently evaluating the impact of the adoption of this accounting standard update on its financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires, among other elements, the excess tax benefits and deficiencies related to employee share-based payment awards and related dividends to be recorded in the statement of operations during the reporting period in which they occur. Additionally, it allows the Company to make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest (consistent with current GAAP) or account for forfeitures when they occur. ASU 2016-09 also requires that all tax-related cash flows resulting from share-based payments, including the excess tax benefits related to the settlement of stock-based awards, be classified as cash flows from operating activities, and that cash paid by directly withholding shares for tax withholding purposes be classified as a financing activity in the Consolidated Statements of Cash Flows. The Company has elected to early adopt ASU 2016-09 in the fourth quarter of fiscal 2016. Amendments requiring recognition of excess tax benefits and tax deficiencies within the Consolidated Statements of Operations were adopted prospectively and resulted in the recognition of no excess tax benefits within income tax (benefit) expense, as any impact is offset by a change in valuation allowance. The Company has elected to continue to estimate forfeitures expected to occur to determine the amount of compensation expense to be recognized in each period. ASU 2016-09 amendments related to presentation within the Consolidated Statements of Cash Flows were applied prospectively and resulted in no reclassification of excess tax benefits related to the settlement of stock-based awards from financing to operating activities, and no taxes paid related to net share settlements of stock-based compensation awards from operating activities to financing activities for the year ended December 31, 2016.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which clarifies the presentation of restricted cash and restricted cash equivalents in the statements of cash flows. Under the ASU, restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts presented on the statements of cash flows. The ASU is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the Consolidated Statement of Cash Flows. The ASU requires that the Consolidated Statement of Cash Flows explain the change in total cash and equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The ASU also requires a reconciliation between the total of cash and equivalents and restricted cash presented on the Consolidated Statement of Cash Flows and the cash and equivalents balance presented on the Consolidated Balance Sheet. The ASU is effective retrospectively on January 1, 2018, with early adoption permitted. The Company does not expect the adoption of the ASU to have a material effect on its results of operations, financial condition or cash flows.

2. Fair Value Measurements

The fair value measurements of the Company's cash equivalents and investments, which are measured at fair value on a recurring basis as of December 31, 2016 and 2015, were determined using the inputs described above and are as follows:

	Total	Fair Value Measurements at Reporting Data Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
December 31, 2016				
Cash and money market funds	$ 81,501	$ 81,501	$ —	$ —
Total assets measured at fair value	$ 81,501	$ 81,501	$ —	$ —
December 31, 2015				
Cash and money market funds	$110,121	$110,121	$ —	$ —
Total assets measured at fair value	$110,121	$110,121	$ —	$ —

The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no significant transfers into or out of Level 1, 2, or 3 for the years ended December 31, 2016 and 2015.

3. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2016	December 31, 2015
	(in thousands)	
Furniture and equipment	$ 350	$ 175
Computers and IT equipment	290	267
Purchased software	869	728
Lab and research equipment	5,022	3,879
Leasehold improvements	739	463
Construction-in-progress	575	1
Other fixed assets	64	64
Total property and equipment, gross	7,909	5,577
Less: accumulated depreciation and amortization	(2,663)	(2,398)
Total property and equipment, net	$ 5,246	$ 3,179

Total property and equipment assets under capital lease were $0.2 million as of December 31, 2016 and 2015. Accumulated depreciation related to assets under capital lease as of these dates were $40 thousand and $19 thousand, respectively. For the years ended December 31, 2016, 2015 and 2014, total depreciation and amortization expense was $0.7 million, $0.5 million, and $0.5 million each year and is included in selling, general and administrative expenses and research and development in the accompanying consolidated statements of operations as follows:

	Years ended December 31,		
	2016	2015	2014
	(in thousands)		
Selling, general and administrative	$ 254	$ 267	$ 366
Research and development	416	274	99
Total depreciation and amortization expense	$ 670	$ 541	$ 465

4. Intangible Assets

Intangible assets consisted of the following:

	December 31,	
	2016	2015
	(in thousands)	
Customer relationships	$ 3,750	$ 3,750
Developed technology	4,400	4,400
Trade names	910	910
Gross intangible assets	9,060	9,060
Less: Accumulated amortization	(3,759)	(3,228)
Total intangible assets, net	$ 5,301	$ 5,832

Amortization expense related to intangible assets was $0.5 million for each of the years ended December 31, 2016, 2015 and 2014. Amortization expense is included within selling, general and administrative expense in the accompanying consolidated statements of operations. As of December 31, 2016, estimated amortization expense for the next five years amounts to approximately $0.5 million per year.

5. Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31,	
	2016	2015
	(in thousands)	
Accrued vacation	$ 553	$ 438
Deferred rent	627	380
Accrued bonuses	1,385	1,239
Other accrued employee-related liabilities	293	205
Accrued professional fees	266	447
Accrued supplier liability	428	90
Accrued subcontractor costs	4,974	2,913
Other accrued liabilities	886	285
Total accrued liabilities	$ 9,412	$ 5,997

6. Lines of Credit Obligation

The Company previously entered into two Revolving Line of Credit agreements with Wells Fargo ("LOCs"), the first of which was entered into in May 2012 ("2012 LOC") and the second in June 2013 ("2013 LOC"). The maximum capacity for the 2012 LOC and 2013 LOC was $1.5 million and $2.4 million, respectively, for a total capacity of $3.9 million. The LOCs were collateralized by money market accounts held at Wells Fargo. In July 2015, the Company and Wells Fargo entered into the Amended and Restated Credit Agreement and the Amended and Restated Revolving Line of Credit Note (together, the "Amended Credit Facility"). The Amended Credit Facility replaced the LOCs and still provided the Company with a $3.9 million revolving line of credit which the Company could draw upon from time to time. The proceeds of the loans under the Amended Credit Facility could be used for working capital and general corporate purposes. In February 2016, the Company terminated the Amended Credit Facility and repaid the approximately $3.8 million outstanding under the Amended Credit Facility using its restricted cash.

The Company recognized $8 thousand, $90 thousand and $85 thousand of interest expense related to the Amended Credit Facility and LOCs for each of the years ended December 31, 2016, 2015 and 2014, respectively.

7. Commitments and Contingencies

Lease Agreements

In June 2010, the Company entered into an operating lease agreement ("Lease") with a landlord for an initial term of 10 years, for its corporate headquarters comprised of one building located in San Diego, California. Occupation of the premises under the Lease began in April 2011. Under the terms of the Lease, the Company pays annual base rent, subject to an annual fixed percentage increase, plus its share of common operating expenses and tax obligations. The annual base rent was subject to abatement of 50% for the first year of the Lease. The Company recognizes rent expense on a straight-line basis over the lease term.

In September 2014, the Company amended the Lease to extend the term for an additional three years through March 31, 2024 and to an additional 7,315 square feet of leased space. The extended term on the existing space increased total estimated rent payments by approximately $1.4 million. Base rent payments for the new space commenced in December 2014 and increased total estimated rent payments over the life of the Lease by approximately $1.5 million. In November 2015, the Company further amended the Lease to add facilities consisting of 16,811 square feet. Base rent payments for the new space commenced in March 2016 and June 2016 and increased total estimated rent payments over the life of the Lease by approximately $2.3 million. In January 2017, a sublease agreement was executed with a tenant to lease a portion of leased space from the Company for eight months. The amounts received are offset against rent expense and are shown as a decrease in commitments.

Rent expense was $0.7 million, $0.5 million, and $0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively, which is included in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations as follows:

	Years Ended December 31,		
	2016	2015	2014
	(in thousands)		
Selling, general and administrative	$375	$290	$279
Research and development	364	248	99
Total rent expense	$739	$538	$378

In addition to the Lease, the Company has entered into operating and capital lease agreements for office and lab equipment that expire at various dates through December 2021.

As of December 31, 2016, the total estimated future annual minimum lease payment obligations under the Company's non-cancelable leasing arrangements, including the facilities lease described above, are as follows:

	Payment Amounts		
	Operating Leases	Capital Leases	Total
		(in thousands)	
2017	$ 1,188	$ 60	$ 1,248
2018	963	13	976
2019	884	13	897
2020	891	13	904
2021 and thereafter	3,048	1	3,049
Total future minimum lease payments	$ 6,974	$ 100	$ 7,074

Clinical Study and Development Activity Commitments

The Company has entered into agreements with contract research organizations and subcontractors to further develop our products. The total contracted costs under these arrangements totaled approximately $20.9 million as of December 31, 2016, of which $5.1 million has been incurred to date. These contracts can be cancelled at any time, with some having certain cancellation fees associated with the termination of the contract, and others that only obligate the Company through the termination date.

Contingencies

From time to time, the Company may be involved in legal proceedings, claims, and litigation in the ordinary course of business. At December 31, 2016 and 2015 there were no material legal proceedings.

8. Common Stock and Preferred Stock

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of other classes of stock outstanding.

Preferred Stock

Pursuant to the amended and restated certificate of incorporation filed by the Company immediately prior to the completion of its IPO, the board of directors is authorized to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in the Company's control or other corporate action. At December 31, 2016, no preferred stock had been issued or was outstanding.

Series A-1 and A-2 Redeemable Convertible Preferred Stock

The Series A-1 and A-2 preferred stock had a contingent redemption feature allowing redemption by the holders at any time after December 31, 2014 upon the affirmative vote of sixty-six and two thirds (66 $^{2}/_{3}$%) of the

holders. As the event that would trigger the redemption of the redeemable convertible preferred stock was not solely within the Company's control, the redeemable convertible preferred stock had been classified as mezzanine equity (outside of permanent equity) on the Company's consolidated balance sheets. The shares were to be redeemed by paying cash in an amount per share equal to the greater of (i) the Series A original issue price and any Series A dividends accrued but unpaid, and (ii) the then-current fair market value of such shares.

The Company immediately recognized the changes in the redemption value as they occurred and the carrying value of the security was adjusted to equal what the redemption amount would be as if redemption were to occur at the end of the reporting date based on the conditions that exist as of that date. There was no limit to the maximum amount the Company could be required to pay. A value adjustment was made to the redemption value at June 30, 2014 as an increase of $0.8 million.

Series A-1 stock was subject to a cumulative dividend of four percent (4%) compounded quarterly, whether or not declared. Each share of Series A-1 stock was convertible into 0.91966 shares of common stock, subject to adjustments for certain dilutive events. Series A-2 stock was subject to a cumulative dividend of eight percent (8%) compounded quarterly, whether or not declared. Each share of Series A-2 stock was convertible into 1.1406 shares of common stock, subject to adjustments for certain dilutive events.

Based on the IPO price of $6.00 per share and the offering closing on July 29, 2014, the Company issued 1,217,784 shares of common stock to holders of its outstanding preferred stock prior to the offering in satisfaction of these accrued dividends through July 28, 2014. Cumulative dividends as of July 28, 2014 and December 31, 2013 were as follows:

	Cumulative as of July 28, 2014	
	Dividends	Dividends per Share
	(in thousands except dividends per share)	
Series A-2	$4,457	$1.25
Series A-1	2,850	$0.57
	$7,307	

9. Commitment to Repurchase Stock

On December 1, 2009, the Company entered into a common stock subscription agreement with three investors ("Investors") pursuant to which the Company agreed to repurchase a maximum of 423,185 shares of common stock at a price per share of $0.31. Pursuant to the amended and restated subscription agreement, dated May 2, 2014, the Company repurchased all 423,185 shares of common stock at $0.31 price per share immediately prior to the completion of the Company's IPO in July 2014. The total cost of the repurchase was $131 thousand.

10. Significant Research and Development Agreements

The Company has two types of research and development agreements (i) those for which the Company receives funding to advance its own products ("Funding Agreements"), and (ii) those for which the Company co-develops or assists customers in developing their products ("Collaboration Agreements").

Funding Agreements

Strides Arcolab Limited

In December 2012, the Company and Stelis Biopharma Private Limited, a subsidiary of Strides Arcolab Limited ("Strides"), entered into a Joint Development & License Agreement ("JDLA"), the purpose of which is

to collaborate to develop certain therapeutic biosimilars through the completion of the first Phase 1 clinical trial. Under the terms of the agreement, Strides is responsible for paying the costs associated with the Phase 1 trials and the manufacturing of the drug product for the trials. Strides is obligated to reimburse the Company for any and all payments made to third-party service providers for Phase 1 trials. As of December 31, 2012 the total of all reimbursable costs was $0.2 million. These reimbursable costs were paid in full to Pfenex in 2013. In March 2013, the Company and Strides entered into a joint venture agreement ("JVA"). The JVA was established to provide a vehicle for the advancement of biosimilars successful in Phase 1 trials under the JDLA. Under the terms of the JVA, both parties share equally in all decisions, and share revenue and costs 51% to Strides and 49% to the Company. As of December 31, 2016, there was no investment in the joint venture by the Company, and there has been no activity in the joint venture ("JV") to date. Once a biosimilar product successfully completes a Phase 1 trial and Strides and the Company agree to contribute the biosimilar to the JV, the JV will incur activity.

The U.S. Department of Health and Human Services

In July 2010, the Company entered into a contract with the Biomedical Advanced Research and Development Authority ("BARDA") within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services to develop a production strain and process for the production of bulk recombinant protective antigen ("rPA") from anthrax. The arrangement is a cost plus fixed fee contract comprised of a base program and follow on options at BARDA's election. At the inception of the contract, both BARDA and the Company entered into the arrangement with the expectation that BARDA would fund all costs of development and no costs in excess of the arrangement would be incurred by the Company. In December 2014, the Company filed the investigational new drug ("IND") application for Px563L. BARDA extended the contract in December 2014 and provided additional funding, increasing the total contract to $25.2 million. The development contract was completed in August 2015.

In August 2015, the Company entered into a contract with BARDA for the advanced development of Px563L as a novel vaccine candidate for the prevention of anthrax infection (the "BARDA Advanced Development Agreement"). The BARDA Advanced Development Agreement is a cost plus fixed fee development contract valued at up to approximately $143.5 million, including a 30 month base period of performance of approximately $15.9 million, and eight option periods valued at a total of approximately $127.6 million. The 30 month base period of performance is from August 2015 through February 2018. In addition to the base period, BARDA exercised additional phases of the development contract effective January 2017, totaling $4.9 million and allowing for the continuing development of Px563L. The phase 2 study could initiate in 2018, provided the program continues to successfully advance with the support of BARDA. The period of performance for the two option periods will be completed within the same base period as described above. Each additional option period, if exercised, would extend the period of performance and the entire contract period of performance would end in August 2020.

Revenue is recognized in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contractors. Reimbursable costs under this government contract primarily include direct labor, materials, subcontracts, accountable property and indirect costs. In addition, the Company receives a fixed fee under the BARDA contract, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under this BARDA contract, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable. The Company recorded revenues of $5.0 million, $3.7 million and $6.6 million for services performed in the years ended December 31, 2016, 2015 and 2014, respectively. Reimbursable costs related to fulfilling on this contract amounted to $3.9 million, $2.9 million and $5.0 million for the years ended December 31, 2016, 2015 and 2014, respectively, and are reflected in cost of revenue in the accompanying consolidated statements of operations. The billing of any overage in indirect cost rates over the approved provisional rates in the contract is not allowed. Any such overage is expensed as incurred. When and if final rates with Defense Contract Audit Agency are approved, the Company will recognize any change in revenue resulting from the rate change in the period such revised rates are approved and as such this would be considered a change

in estimate. This agreement is subject to early termination and stop-work order in conformance with Federal Acquisition Regulations 52.249-6 and 52.242-15 whereupon BARDA may immediately terminate the agreement early for convenience, or request the Company to stop all or any part of the work for a period of at least 90 days. If BARDA is not adequately funded, there is a potential that some or all of the follow on options could be delayed or never elected.

The National Institute of Allergy and Infectious Diseases

In September 2012, the Company entered into a contract with the National Institute of Allergy and Infectious Diseases ("NIAID") to provide services to advance vaccine components and technologies that accelerate the immune response for use in post-event settings following the intentional release of the NIAID Category A Priority Pathogen Bacillus anthracis or in response to naturally occurring outbreaks of infectious diseases caused by NIAID Category A Priority Pathogen B. anthracis. The arrangement is a cost plus fixed fee contract comprised of a base program and 13 follow-on options at NIAID's election. At the inception of the contract, both NIAID and the Company entered into the arrangement with the expectation that NIAID would fund all costs of development and no costs in excess of the arrangement would be incurred by the Company. The total amount of the contract including options is $22.9 million, with $2.2 million eligible for payment during the base program of approximately 14 months. The fixed fee is paid as specific activities are completed. NIAID exercised the first option period effective in January 2015, increasing the funding to $3.0 million. NIAID exercised the second option period effective May 2016, increasing the funding to approximately $4.1 million. The contract has been extended through the end of December 31, 2017.

Revenue is recognized in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contractors. Reimbursable costs under this government contract primarily include direct labor, subcontracts and indirect costs. In addition, the Company receives a fixed fee under the NIAID contract, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under this NIAID contract, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable. The Company recorded revenues of $0.5 million, $0.9 million and $1.0 million for services performed in the years ended December 31, 2016, 2015 and 2014, respectively. Reimbursable costs related to fulfilling this contract amounted to $0.4 million, $0.5 million and $0.5 million for the years ended December 31, 2016, 2015 and 2014, respectively, and are reflected in cost of revenues in the accompanying consolidated statements of operations. The billing of any overage in indirect cost rates over the approved provisional rates in the contract is not allowed. Such overage is expensed as incurred. When and if final rates with Defense Contract Audit Agency are approved, the Company will recognize any change in revenue resulting from the rate change in the period such revised rates are approved and as such this would be considered a change in estimate. This agreement is subject to early termination and stop-work order in conformance with Federal Acquisition Regulations 52.249-6 and 52.242-15 wherein NIAID may immediately terminate the agreement early for convenience, or request the Company to stop all or any part of the work for a period of at least 90 days. If NIAID is not adequately funded, there is a potential that some or all of the follow on options could be delayed or never elected.

Collaboration and License Agreements

Pfizer

In February 2015, the Company entered into a development and license agreement ("Pfizer Agreement") with Pfizer for the development and commercialization of PF582. Under the terms of the Pfizer Agreement, in March of 2015 the Company received a non-refundable license payment of $51 million on receipt of antitrust approval. Following Pfizer's strategic review of the current therapeutic focus of its biosimilar pipeline, the Company and Pfizer entered into a termination agreement in August 2016, pursuant to which the Pfizer

Agreement was terminated and all rights to PF582 were returned to the Company. Upon termination, $45.8 million of previously deferred revenue was recognized. For the years ended December 31, 2016 and 2015, $48.0 and $3.0 million was recognized as license revenue related to the Pfizer Agreement, respectively.

Jazz

In July 2016, the Company entered into the Jazz Agreement for the development and commercialization of multiple early stage hematology product candidates. The agreement also includes an option for Jazz to negotiate a license for a recombinant pegaspargase product candidate with the Company. Under the Jazz Agreement, Pfenex received an upfront and option payment totaling $15 million in July 2016 and may be eligible to receive additional payments of up to $166 million based on achievement of certain research and development, regulatory and sales related milestones, including up to approximately $41 million for certain non-sales-related milestones. The total milestones are categorized as follows: $7 million are based on achievement of certain research and development milestones; $34 million for certain regulatory milestones; and $125 million for sales milestones. For the non-sales-related milestones, the Company conducted an evaluation whether they will be recorded using the milestone method and as a result of this evaluation, estimates approximately $7.0 million of these non-sales-related milestones are deemed to be substantive. The Company may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. Both Jazz and the Company will be contributing to the development efforts. Unless terminated earlier, the Jazz Agreement will continue on a product-by-product basis for as long as Jazz is commercializing or having commercialized the products under the Jazz Agreement.

In accordance with ASC 605-25, the Company identified all of the deliverables at the inception of the Jazz Agreement. The significant deliverables were determined to be the research and development services related to the pegaspargase product candidate option and for license and research and development activities of the other hematology products. The Company has determined that the license, together with the research and development activities, represent one unit of accounting for each product under license, as the license does not have standalone value from the respective development activities. The research and development activities related to the pegaspargase option were determined to have standalone value apart from the license and development activities for the other hematology products. The estimated selling price for the Pegaspargase product candidate and the hematology products was determined using an income approach. In determining the estimated selling price, we considered costs expected to be incurred for internal labor, burden rates, internal margins, and subcontractors. Based on our considerations of estimated selling price, we allocated $10 million to the Pegaspargase product candidate and $2.5 million to each of the hematology products. The upfront and option payment is being deferred and will be recognized as revenue ratably over the period in which the Company expects services to be rendered for each respective unit of accounting, which approximates a range of 15 to 32 months. During the year ended December 31, 2016, the Company recorded revenue of approximately $3.6 million related to the Jazz Agreement.

Boehringer Ingelheim International GmbH

Effective December 2010, the Company entered into a three-year transaction agreement with Boehringer Ingelheim International GmbH (“BII”) to provide BII with access to the Company’s proprietary technology to express BII and BII’s clients’ proteins. During the collaboration, BII had the option to obtain a commercial license for up to four designated proteins. All collaborations and licenses under the agreement are nonexclusive. Under the terms of the agreement, BII paid the Company an annual technology fee of $0.2 million and guaranteed a minimum fee of $0.6 million. Additionally, for providing protein expression services, BII paid the Company approximately $0.4 million per protein expression program with a guaranteed minimum of $1.0 million during the term of the agreement.

The Company evaluated each of the deliverables included within the BII agreement and concluded the underlying deliverables met the criteria to be considered separate units of accounting; therefore, the annual technology maintenance fee was recognized in equal monthly installments over the related 12-month period, and revenue associated with the feasibility service fees was recognized as the services were performed.

The Company recognized feasibility revenue of $1.0 million for services performed during the year ended December 31, 2014. All performance obligations pursuant to the contract were completed during 2014. No

deferred revenues were recorded as of December 31, 2016, 2015 or 2014, and no revenue related to the contract was recorded during the years ended December 31, 2016 or 2015.

11. Stock-Based Compensation

Summary Stock-Based Compensation Information

The following table summarizes stock-based compensation expense:

	Years Ended December 31,		
	2016	2015	2014
		(in thousands)	
Cost of revenues	$ 225	$ 124	$ 49
Research and development	822	371	47
Selling, general and administrative	2,109	1,345	308
Total	$ 3,156	$ 1,840	$ 404

	Years Ended December 31,		
	2016	2015	2014
		(in thousands)	
Stock-based compensation from:			
Stock options	$ 2,983	$ 1,761	$ 404
Employee stock purchase plan	173	79	—
Total	$ 3,156	$ 1,840	$ 404

Stock Option Plan

The Company's board of directors adopted, and the Company's stockholders approved, the Company's 2009 Equity Incentive Plan ("2009 Plan") in 2009. The 2009 Plan terminated in connection with the Company's IPO in 2014 and, accordingly, no awards will be granted under the 2009 Plan following the IPO. However, the 2009 Plan will continue to govern outstanding awards granted thereunder. An aggregate of 1.1 million shares of common stock was reserved for issuance under the 2009 Plan. The 2009 Plan provided for the grant of incentive stock options and for the grant of nonstatutory stock options, restricted stock, restricted stock units, and stock appreciation rights to the Company's employees, directors and consultants. As of December 31, 2016, awards covering 0.5 million shares of common stock were outstanding under the 2009 Plan.

In July 2014, the board of directors adopted a 2014 Equity Incentive Plan ("2014 Plan") and the Company's stockholders approved it. The 2014 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants and parent and subsidiary corporations' employees and consultants. The shares available for issuance under the 2014 Plan include shares returned to the 2009 Plan as the result of expiration or termination of awards (provided that the maximum number of shares that may be added to the 2014 Plan pursuant to such previously granted awards under the 2009 Plan is 961,755 shares). The number of shares available for issuance under the 2014 Plan also includes an annual increase on the first day of each fiscal year beginning in 2015 and ending with and including the 2018 fiscal year, equal to the least of: (i) 1,356,219 shares; (ii) 2.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as the board of directors may determine. As of December 31, 2016, a total of 595,928 shares of common stock were available for issuance pursuant to the 2014 Plan. As of December 31, 2016, awards covering 1.9 million shares of common stock were outstanding under the 2014 Plan.

In September 2016, the board of directors adopted the 2016 Inducement Equity Incentive Plan ("2016 Plan"). The 2016 Plan provides for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to new employees. Stock options granted under the 2016 Plan have a term of ten years from the date of grant, the exercise price for the shares to be issued will be no less than 100% of the fair market value per share on the date of grant and generally vest over a four-year period. The maximum aggregate number of shares that may be issued under the 2016 Plan is 500,000 shares. As of December 31, 2016, a total of 313,710 shares of common stock were available for issuance pursuant to the 2016 Plan. As of December 31, 2016, awards covering 0.2 million shares of common stock were outstanding under the 2016 Plan.

Stock options granted to date under the 2009 Plan and the 2014 Plan have a term of ten years from the date of grant, and generally vest over a four-year period. However, in the event that an incentive stock option ("ISO") granted to a participant who, at the time the ISO is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company, the term of the ISO shall be five years from the grant date or such shorter term as may be provided in the award agreement.

In July 2014, the board of directors adopted the 2014 Employee Stock Purchase Plan ("ESPP") and the stockholders approved it. As of December 31, 2016, a total of 952,402 shares of common stock were available for issuance under the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for sale under the ESPP on the first day of each fiscal year beginning in 2015, equal to the least of: (i) 355,618 shares; (ii) 1.5% of the outstanding shares of the common stock on the last day of the immediately preceding fiscal year; or (iii) such other amount as may be determined by the administrator. As of December 31, 2016, 59,037 shares have been purchased under the ESPP.

Stock Options

The exercise price of all options granted during the years ended December 31, 2016, 2015 and 2014 was equal to the estimated fair value of the underlying common stock on the date of grant. The fair value of each stock option granted is estimated on the grant date under the fair value method using the Black-Scholes model. The estimated fair values of the stock option, including the effect of estimated forfeitures, are then expensed over the requisite service period which is generally the vesting period. The following assumptions were used to estimate the fair value of stock options:

	Years Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.1 – 2.0%	1.3 – 1.9%	1.7 – 2.0%
Expected volatility	63.1 – 68.6%	49.8 – 68.2%	48.7 – 55.0%
Expected dividend yield	0.0%	0.0%	0.0%
Expected life of options in years	5.1-6.3	6.0	5.3-6.1

The fair value of equity instruments that are ultimately expected to vest, net of estimated forfeitures, are recognized and amortized on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model requires multiple subjective inputs, including a measure of expected future volatility. Prior to the Company's IPO, the Company's stock did not have a readily available market. Consequently, the expected future volatility was based on the historical volatility for comparable publically traded companies over the most recent period commensurate with the estimated expected term of the Company's stock options. Beginning in the fourth quarter of 2016, the expected future volatility was based on the historical volatility for the Company's common stock. Following the completion of the Company's IPO in July 2014, the fair value of options granted is based on the closing price of the Company's common stock on the date of grant as quoted on the NYSE MKT.

The risk-free interest rate assumption is based upon observed interest rates during the period appropriate for the expected term of the options. The expected term of the options has been estimated using the simplified

method to determine the expected life of the Company's options due to insufficient activity as a basis from which to estimate future exercise patterns. With the exception of 1,217,784 shares of common stock issued in connection with the payment of all accrued and unpaid dividends on the preferred stock immediately prior to the completion of the Company's IPO, the Company had never declared or paid dividends and has no plans to do so in the foreseeable future. Accordingly, the dividend yield assumption is based on the expectation that the Company will not pay dividends on its common stock in the future. Authoritative guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The weighted-average grant date fair value of options granted during the year ended December 31, 2016, 2015 and 2014 was $5.47, $5.91 and $4.60 respectively. Total fair value of shares vested during the years ended December 31, 2016, 2015 and 2014 was $972 thousand, $971 thousand and $137 thousand, respectively.

Stock option transactions under the 2009, 2014 and 2016 Plans during the year ended December 31, 2016 were as follows:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2016	1,638	8.50		
Granted	1,167	8.87		
Exercised	(78)	1.57		
Cancelled (forfeited)	(156)	12.85		
Outstanding at December 31, 2016	2,571	$ 8.62	7.96	$3,135
Vested and expected to vest at December 31, 2016	2,346	$ 8.55	6.67	$3,996
Vested and exercisable at December 31, 2016	972	$ 7.53	6.67	$3,135

The Company received $123 thousand, $201 thousand and $56 thousand for the years ended December 31, 2016, 2015 and 2014, respectively, for options exercised. Options outstanding at December 31, 2016 have a weighted-average remaining contractual term of 7.96 years.

As of December 31, 2016, there was approximately $6.5 million of unrecognized compensation cost related to unvested stock option awards, and the weighted-average period over which this cost is expected to be recognized is 2.79 years.

The total aggregate intrinsic value, which is the amount, if any, by which the exercise price was exceeded by the estimated fair value of the Company's common stock, of options exercised, was $0.6 million, $4.7 million and $0.8 million for the years ended December 31, 2016, 2015 and 2014, respectively.

12. Retirement Plan

The Company has a 401(k) Savings Plan ("401(k)"). The 401(k) is for the benefit of all qualifying employees and permits voluntary contributions by employees up to a maximum percentage allowable by current IRS regulations. During the year ended December 31, 2016, the Company made matching contributions to the 401(k) of $197 thousand. During the years ended December 31, 2015 and 2014, the Company did not match employee contributions.

13. Income Taxes

The components of the income tax (benefit) expense are as follows:

	Years Ended December 31,		
	2016	2015	2014
		(in thousands)	
Current	$(2,164)	$ (680)	$(1,047)
Deferred	1,955	1,132	1,047
Total (benefit) expense	$ (209)	$ 452	$ —

During the year ended December 31, 2016, the Company recorded an income tax benefit of $0.2 million attributable to state income tax and the refundable Alternative Minimum Tax Credit. For the year ended December 31, 2015, the Company recorded an income tax expense of $0.5 million attributable to U.S. federal alternative minimum tax and state income tax. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's balance sheet as of December 31, 2016 and 2015 and the Company did not recognize any interest and/or penalties in its consolidated statements of operations during the years ended December 31, 2016, 2015, or 2014. The Company is subject to income tax in the United States, California, Massachusetts and India. The Company currently has no years under examination by any jurisdiction; however, the Company is subject to income tax examination by federal and various state tax authorities for the years beginning in 2012 due to federal and state statutes.

For tax purposes, the Company recognized all of the $51 million upfront payment from Pfizer as income during the year ended December 31, 2015. The Company also established a deferred tax asset for the difference between the income recognized for book and tax during the year ended December 31, 2015. The contract with Pfizer was terminated in August 2016, at which time the entire deferred tax asset of $48 million was reversed. The reversal of the deferred revenue will provide for a carryback to the 2015 tax year, resulting in a net tax provision for federal alternative minimum tax of $0.4 million which was recorded during the year ended December 31, 2015.

As of December 31, 2016, the Company had federal and state research and development credits carryforwards of approximately $2.7 million and $1.7 million, respectively, to offset potential tax liabilities. The federal research and development credits have a 20-year carryforward period and begin to expire in 2030 unless utilized. California research and development tax credits have no expiration. The Company has $19.9 million federal net operating loss carryforwards and $11.8 million of state net operating loss carryforwards as of December 31, 2016. The federal and state net operating losses can be carried forward until 2036 unless utilized.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards and found that a greater than 50% cumulative change in ownership occurred in August 2014 in conjunction with the Company's IPO. The Company has significant built-in gains; therefore all the pre-change net operating losses were available for utilization.

Significant components of the Company's deferred tax assets as of December 31, 2016 and 2015 are shown below. A valuation allowance of $14.5 million for the year ended December 31, 2016 has been established to offset deferred tax assets as realization of such assets is uncertain.

	December 31,	
	2016	2015
	(in thousands)	
Deferred tax assets		
Net operating losses	$ 7,442	$ 12
Stock-based compensation	1,069	535
Research and development credits	3,456	1,225
Deferred revenue	4,166	16,506
Accruals and other	846	844
Total deferred tax assets	16,979	19,122
Deferred tax liabilities		
Depreciation and amortization	(629)	(757)
Intangible assets	(1,867)	(2,058)
Total deferred tax liabilities	(2,496)	(2,815)
Valuation allowance	(14,483)	(14,352)
Net deferred tax asset	$ —	$ 1,955

A reconciliation of the Company's effective tax rate and federal statutory tax rate at December 31, 2016, 2015 and 2014 is as follows:

	December 31,		
	2016	2015	2014
		(in thousands)	
Federal income taxes	$ 1,792	$(9,440)	$(3,330)
State income taxes	190	(673)	(567)
State rate changes	(1,080)	743	(2)
Stock-based compensation	489	(117)	75
Valuation allowance	130	9,984	3,994
Research and development credits	(1,683)	(815)	(165)
Permanent items and other	(47)	770	(5)
Total income tax (benefit) expense	$ (209)	$ 452	$ —

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company established an uncertain tax position with respect to its research and development credits as of December 31, 2016.

Following is a tabular reconciliation of the Company's Unrecognized Tax Benefits activity (excluding interest and penalties):

	December 31,		
	2016	2015	2014
	(in thousands)		
Beginning balance of unrecognized tax benefits	$301	$ —	$ —
Additions based on tax positions related to the current year	369	162	—
Additions based on tax positions of prior years	79	139	—
Reductions for tax positions of prior years	(19)	—	—
Settlements	—	—	—
Reductions due to lapse in statute of limitations	—	—	$ —
Reductions for tax positions of the prior year	$730	$ 301	$ —

As of December 31, 2016, if recognized, approximately $0.7 million would affect the effective tax rate if the Company did not have a valuation allowance.

The Company does not anticipate significant increases or decreases within the next 12 months with respect to its unrecognized tax benefit.

14. Net Income (Loss) Per Share of Common Stock

The following table summarizes the computation of basic and diluted net income (loss) per share attributable to common stockholders of the Company:

	December 31,		
	2016	2015	2014
	(in thousands, except per share data)		
Net income (loss)	$ 5,481	$(28,216)	$(9,794)
Weighted average shares used to compute basic net income (loss) per share	23,389	22,376	9,441
Dilutive effect of employee stock option plans	299	—	—
Dilutive weighted-average common shares outstanding	23,688	22,376	9,441
Basic net income (loss) per common share	$ 0.23	$ (1.26)	$ (1.04)
Diluted net income (loss) per common share	$ 0.23	$ (1.26)	$ (1.04)

The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computation of diluted shares outstanding because of their anti-dilutive impact to earnings per share:

	December 31,		
	2016	2015	2014
	(in thousands)		
Options to purchase common stock	1,774	1,638	1,232
ESPP	60	33	45

15. Quarterly Financial Data (unaudited)

The following is a summary of the quarterly results of the Company for the years ended December 31, 2016 and 2015:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year Ended December 31
	(in thousands, except for per share data)				
2016					
Revenues	$ 2,764	$ 3,135	$48,824	$ 5,471	$ 60,194
Cost of revenues	1,276	1,440	1,285	1,312	5,313
Gross profit	1,488	1,695	47,539	4,159	54,881
Operating expenses	9,696	11,907	13,095	15,060	49,758
Other income, net	—	46	52	51	149
Income tax benefit (expense)	(1)	—	—	210	209
Net income (loss)	(8,209)	(10,166)	34,496	(10,640)	5,481
Net income (loss) per share:					
Basic	$ (0.35)	$ (0.43)	$ 1.47	$ (0.45)	$ 0.23
Diluted	$ (0.35)	$ (0.43)	$ 1.46	$ (0.45)	$ 0.23
Shares used in the calculation of net income (loss) per share:					
Basic	23,353	23,379	23,400	23,424	23,389
Diluted	23,353	23,379	23,689	23,424	23,688
2015					
Revenues	$ 1,975	$ 2,290	$ 2,057	$ 3,261	$ 9,583
Cost of revenues	1,308	921	682	1,729	4,640
Gross profit	667	1,369	1,375	1,532	4,943
Operating expenses	6,700	7,298	8,955	9,828	32,781
Other income (expense), net	80	(33)	(9)	36	74
Income tax expense	(19)	(21)	(1)	(411)	(452)
Net loss	(5,972)	(5,983)	(7,590)	(8,671)	(28,216)
Net loss per share:					
Basic and Diluted	$ (0.29)	$ (0.27)	$ (0.33)	$ (0.37)	$ (1.26)
Shares used in the calculation of net loss per share:					
Basic and Diluted	20,474	22,460	23,215	23,295	22,376

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Interim Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and

procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon that evaluation, the Interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2016, due to the material weakness in internal control over financial reporting that is described below. Notwithstanding the material weakness in our internal control over financial reporting as of December 31, 2016, management has concluded that the consolidated financial statements included in this Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, management has concluded that its internal control over financial reporting was ineffective as of December 31, 2016 due to the existence of a material weakness.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We did not maintain an effective control environment as our former Chief Executive Officer failed to set an appropriate "Tone at the Top." Specifically, our former Chief Executive Officer failed to act in accordance with our Board Approval Process Policy and Code of Ethics and Conduct as a result of his failure to comply with certain board approval procedures for third-party contracts. This control deficiency did not result in a misstatement to our consolidated financial statements. However, this control deficiency could have resulted in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that this control deficiency constitutes a material weakness.

Our independent registered public accounting firm, KPMG LLP, is not required to and has not issued an attestation report as of December 31, 2016 due to a transition period established by the rules of the SEC for newly public companies that have not lost their "emerging growth company" status as defined in the JOBS Act.

Remediation Plan and Activities

Management, with the participation and input of the audit committee and the board of directors, is engaged in remedial activities to address the material weakness described above. The remedial activities include the following:

- A change in our Chief Executive Officer when our board appointed a new Interim Chief Executive Officer, President, and Secretary following the resignation of our former Chief Executive Officer on January 23, 2017;
- Requiring documentation of approvals for contracts that implicate the Board Approval Process Policy;
- Increasing the frequency of our internal audit testwork to assess the design, implementation, and operating effectiveness of our entity level and process level controls; and

- Increasing communication with, and training of employees regarding:
  - Our commitment to ethical standards and the integrity of our business practices;
  - Requirements for compliance with our Board Approval Process Policy and Code of Ethics and Conduct, including training of new hires and re-training of existing employees; and
  - Availability of and processes for reporting suspected violations of our Code of Ethics and Conduct.

We are committed to maintaining a strong internal control environment, and we believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate this material weakness in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weakness in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weakness expeditiously.

Changes in Internal Control Over Financial Reporting

During the three months ended December 31, 2016, we identified a material weakness in our internal control over financial reporting because our former Chief Executive Officer failed to set an appropriate "Tone at the Top." As described above under "*Remediation Plan and Activities*," we have been taking steps to remediate the material weakness identified above.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2016 fiscal year.

Codes of Ethics and Conduct

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers, and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. The full text of our Code of Ethics and Conduct is posted on the Investors portion of our website at http://pfenex.investorroom.com/. We will post amendments to our Code of Ethics and Conduct or waivers of our Code of Ethics and Conduct for directors and executive officers on the same website.

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2016 fiscal year.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2016 fiscal year.

Item 13. ***Certain Relationships and Related Transactions and Director Independence***

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2016 fiscal year.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2016 fiscal year.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this report:

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

	Years Ended December 31,		
	2016	2015	2014
	(in thousands)		
Allowance for Doubtful Accounts:			
Beginning balance	$ 408	$ 585	$ 44
Charged to costs and expenses	—	0	559
Reductions and write-offs	(358)	(177)	(18)
Ending balance	$ 50	$ 408	$585

All other schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

3. Exhibits

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 15, 2017

Pfenex Inc.

By: /s/ Patrick K. Lucy
Patrick K. Lucy
Interim Chief Executive Officer, President, and Secretary, and Chief Business Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Patrick K. Lucy and Paul A. Wagner, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Patrick K. Lucy Patrick K. Lucy	Interim Chief Executive Officer, President, and Secretary, and Chief Business Officer *(Principal Executive Officer)*	March 15, 2017
/s/ Paul A. Wagner Paul A. Wagner	Chief Financial Officer *(Principal Financial Officer)*	March 15, 2017
/s/ Patricia Lady Patricia Lady	Chief Accounting Officer *(Principal Accounting Officer)*	March 15, 2017
/s/ William R. Rohn William R. Rohn	Chairman and Director	March 15, 2017
/s/ Robin D. Campbell Robin D. Campbell	Director	March 15, 2017
/s/ Dennis Fenton Dennis Fenton	Director	March 15, 2017
/s/ Phillip M. Schneider Phillip M. Schneider	Director	March 15, 2017
/s/ John Taylor John Taylor	Director	March 15, 2017

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-36540	3.2	July 29, 2014
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-196539	3.3	June 5, 2014
4.1	Specimen Stock Certificate.	S-1/A	333-196539	4.1	June 23, 2014
4.2	Investors' Rights Agreement, dated December 1, 2009, as amended, by and among the Registrant and the investors named therein.	S-1/A	333-196539	4.2	July 7, 2014
4.3	Amended and Restated Subscription Agreement, dated May 2, 2014.	S-1	333-196539	4.3	June 5, 2014
10.1+	2009 Equity Incentive Plan and form of award thereunder.	S-1	333-196539	10.1	June 5, 2014
10.2+	2014 Equity Incentive Plan and form of award thereunder.	S-1/A	333-196539	10.2	July 17, 2014
10.3+	2014 Employee Stock Purchase Plan.	S-1/A	333-196539	10.3	July 7, 2014
10.4+	2016 Inducement Equity Incentive Plan and forms of award thereunder.	10-Q	001-36540	10.4	November 9, 2016
10.5	Form of Indemnification Agreement.	S-1	333-196539	10.4	June 5, 2014
10.6	Lease Agreement, dated June 22, 2010, between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	S-1	333-196539	10.5	June 5, 2014
10.7	First Amendment to Multi-Tenant Industrial/ Commercial Lease dated September 4, 2014 between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	8-K	001-36540	10.1	September 25, 2014
10.8	Second Amendment to Multi-Tenant Industrial/Commercial Lease dated November 19, 2015 between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	10-K	001-36540	10.7	March 10, 2016
10.9	Third Amendment to Multi-Tenant Industrial/Commercial Lease dated February 24, 2016 between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	10-Q	001-36540	10.2	May 9, 2016
10.10†	Joint Development & License Agreement, dated December 31, 2012, between the Registrant and Agila Biotech Private Limited.	S-1/A	333-196539	10.6	June 25, 2014

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.11†	Joint Venture Agreement, dated March 7, 2013, between the Registrant and Agila Biotech Private Limited.	S-1/A	333-196539	10.7	June 25, 2014
10.12†	Technology License Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1/A	333-196539	10.8	June 25, 2014
10.13	Grant Back License Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1	333-196539	10.9	June 5, 2014
10.14	Technology Assignment Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1	333-196539	10.10	June 5, 2014
10.15	Contribution Assignment and Assumption Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1	333-196539	10.11	June 5, 2014
10.16†	Subcontract Agreement, effective September 11, 2009, between the Registrant, as assignee of The Dow Chemical Company, and Science Applications International Corporation.	S-1/A	333-196539	10.12	June 25, 2014
10.17†	Subcontract Agreement, Modification 21, effective September 12, 2014, between the Registrant, as assignee of The Dow Chemical Company, and Science Applications International Corporation.	10-Q	001-36540	10.4	November 14, 2014
10.18†	Cost Plus Fixed Fee Agreement, dated July 30, 2010, as amended December 18, 2014, between the Registrant and the United States Department of Health and Human Services.	10-K	001-36540	10.15	March 16, 2015
10.19	Modification No. 11, effective January 5, 2015, to Contract Agreement dated July 30, 2010, between the Registrant and the United States Department of Health and Human Services	10-Q	001-36540	10.6	May 14, 2015
10.20	Modification No. 12, effective May 5, 2015, to Contract Agreement dated July 30, 2010, between the Registrant and the United States Department of Health and Human Services.	10-Q	001-36540	10.1	August 13, 2015
10.21	Modification No. 13, effective July 23, 2015, to Contract Agreement dated July 30, 2010, between the Registrant and the United States Department of Health and Human Services.	10-Q	001-36540	10.2	November 13, 2015

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.22†	Modification No. 14, effective October 20, 2015, to Contract Agreement dated July 30, 2010, between the Registrant and the United States Department of Health and Human Services.	10-K	001-36540	10.20	March 10, 2016
10.23†	Modification No. 15, effective March 14, 2016, to Contract Agreement dated July 30, 2010, between the Registrant and the United States Department of Health and Human Services.	10-Q	001-36540	10.4	May 9, 2016
10.24	Credit Agreement, dated May 1, 2012, as amended, between the Registrant and Wells Fargo Bank, National Association.	S-1	333-203418	10.16	April 15, 2015
10.25	Third Amendment to Credit Agreement, dated December 11, 2014, between the Registrant and Wells Fargo Bank, National Association.	10-K	001-36540	10.17	March 16, 2015
10.26	Amended and Restated Credit Agreement, dated July 1, 2015, between the Registrant and Wells Fargo Bank, National Association.	8-K	001-36540	10.1	July 6, 2015
10.27	First Amendment to Amended and Restated Credit Agreement, dated September 28, 2015, between the Registrant and the Wells Fargo Bank, National Association.	10-Q	001-36540	10.3	November 13, 2015
10.28	Security Agreement, dated May 1, 2012, between the Registrant and Wells Fargo Bank, National Association.	S-1	333-196539	10.15	June 5, 2014
10.29	Security Agreement, dated June 24, 2013, between the Registrant and Wells Fargo Bank, National Association.	S-1	333-196539	10.17	June 5, 2014
10.30	Security Agreement dated June 24, 2014 between the Registrant and Wells Fargo Bank, National Association.	S-1/A	333-196539	10.28	July 7, 2014
10.31	Revolving Line of Credit Note, dated May 1, 2012, between the Registrant and Wells Fargo Bank, National Association.	S-1	333-203418	10.19	April 15, 2015
10.32	Revolving Line of Credit Note, dated June 24, 2013, between the Registrant and Wells Fargo Bank, National Association.	S-1	333-203418	10.21	April 15, 2015
10.33	Amended and Restated Revolving Line of Credit Note, dated July 1, 2015, between the Registrant and Wells Fargo Bank, National Association.	8-K	001-36540	10.2	July 6, 2015

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.34	Securities Account Control Agreement, dated June 24, 2013, between the Registrant and Wells Fargo Bank, National Association.	S-1	333-196539	10.19	June 5, 2014
10.35+	Executive Employment Agreement, dated June 20, 2014, between the Registrant and Bertrand C. Liang.	S-1/A	333-196539	10.20	June 23, 2014
10.36+	Executive Employment Agreement, dated June 20, 2014, between the Registrant and Paul A. Wagner.	S-1/A	333-196539	10.21	June 23, 2014
10.37+	Executive Employment Agreement, dated June 20, 2014, between the Registrant and Patricia Lady.	S-1/A	333-196539	10.22	June 23, 2014
10.38+	Executive Employment Agreement, dated June 20, 2014, between the Registrant and Patrick K. Lucy.	S-1/A	333-196539	10.23	June 23, 2014
10.39+	Executive Employment Agreement, dated June 20, 2014, between the Registrant and Henry W. Talbot.	S-1/A	333-196539	10.24	June 23, 2014
10.40+	Executive Employment Agreement, dated November 3, 2014, between the Registrant and Hubert C. Chen.	10-K	001-36540	10.29	March 16, 2015
10.41+	Executive Employment Agreement, dated September 26, 2016, between the Registrant and Steven Sandoval, Sr.	10-Q	001-36540	10.3	November 9, 2016
10.42+	Separation Agreement and Release by and between the Company and Bertrand C. Liang effective January 23, 2017.	8-K	001-36540	10.1	January 24, 2017
10.43+	Consulting Agreement by and between the Company and Bertrand C. Liang effective January 23, 2017.	8-K	001-36540	10.2	January 24, 2017
10.44+	Executive Incentive Compensation Plan.	S-1/A	333-196539	10.27	June 23, 2014
10.45†	Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	S-1/A	333-196539	10.25	June 25, 2014
10.46	Modification No. 3, dated October 31, 2014, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	10-K	001-36540	10.32	March 16, 2015
10.47†	Modification No. 4, dated January 5, 2015, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	10-K	001-36540	10.33	March 16, 2015

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.48†	Modification No. 5, dated April 5, 2015, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	S-1	333-203418	10.34	April 15, 2015
10.49†	Modification No. 6, dated November 2, 2015, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	10-K	001-36540	10.43	March 10, 2016
10.50†	Modification No. 7, dated February 22, 2016, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	10-Q	001-36540	10.3	May 9, 2016
10.51†	Modification No. 8, dated May 16, 2016, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	10-Q	001-36540	10.1	August 8, 2016
10.52†	Modification No. 9, effective September 28, 2016, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.	10-Q	001-36540	10.2	November 9, 2016
10.53#*	Modification No. 10, effective October 31, 2016, to Contract Agreement, dated September 27, 2012, between the Registrant and the National Institutes of Health.				
10.54†	Development and License Agreement, dated February 9, 2015, between the Registrant and Hospira Bahamas Biologics Ltd.	S-1/A	333-203418	10.35	April 23, 2015
10.55†	Cost Plus Fixed Fee Agreement, dated August 14, 2015 between the Registrant and the United States Department of Health and Human Services.	10-Q/A	001-36540	10.1	February 23, 2016
10.56†	Modification No. 1, effective October 15, 2015, to Cost Plus Fixed Fee Agreement, dated August 14, 2015, between the Registrant and the United States Department of Health and Human Services.	10-K	001-36540	10.46	March 10, 2016
10.57†	Modification No. 2, effective February 17, 2016, to Cost Plus Fixed Fee Agreement, dated August 14, 2015, between the Registrant and the United States Department of Health and Human Services.	10-Q	001-36540	10.1	May 9, 2016

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.58#*	Modification No. 3, effective November 29, 2016, to Cost Plus Fixed Fee Agreement, dated August 14, 2015, between the Registrant and the United States Department of Health and Human Services.				
10.59#*	Modification No. 4, effective January 9, 2017, to Cost Plus Fixed Fee Agreement, dated August 14, 2015, between the Registrant and the United States Department of Health and Human Services.				
10.60†	License and Option Agreement, dated July 27, 2016, by and between the Registrant and Jazz Pharmaceuticals Ireland Limited.	10-Q	001-36540	10.1	November 9, 2016
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.				
23.2*	Consent of Haskell & White, LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained on signature page).				
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1^	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

^ The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), and is not to be incorporated by reference into any filing of Pfenex Inc. under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

† Portions of the exhibit have been omitted pursuant to an order granted by the Securities and Exchange Commission for confidential treatment.

Portions of this exhibit have been omitted pursuant to a request for confidential treatment and the non-public information has been filed separately with the SEC.

\+ Indicates a management contract or compensatory plan.

BOARD OF DIRECTORS

William R. Rohn
Chairman
Former Chief Operating Officer of Biogen Idec

Robin D. Campbell
Technology Management Program Lecturer at the University of California, Santa Barbara

Phillip M. Schneider
Former Senior Vice President and Chief Financial Officer at IDEC Pharmaceuticals Corporation

Dennis M. Fenton
Former Executive Vice President at Amgen, Inc.

John M. Taylor
President and Principal of Compliance and Regulatory Affairs at Greenleaf Health LLC

CORPORATE EXECUTIVES

Patrick K. Lucy
Interim Chief Executive Officer, President, and Secretary, and Chief Business Officer

Paul A. Wagner
Chief Financial Officer

Patricia Lady
Chief Accounting Officer

Hubert C. Chen
Chief Medical Officer

Steven S. Sandoval Sr.
Chief Manufacturing Officer

CORPORATE HEADQUARTERS

Pfenex Inc.
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San Diego, CA 92121
T: (858) 352-4400
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www.pfenex.com

COMMON STOCK LISTING

NYSE MKT
Ticker Symbol: PFNX

ANNUAL MEETING OF STOCKHOLDERS

May 5, 2017 at 12:00 p.m. Pacific Time
Offices of Wilson Sonsini Goodrich & Rosati, P.C.
12235 El Camino Real, Suite 200
San Diego, CA 92130

REGISTRAR AND TRANSFER AGENT

For questions regarding your account, changes of address or the consolidation of accounts, please contact the Company's transfer agent:

American Stock Transfer & Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
T: 800-937-5449
www.amstock.com

LEGAL COUNSEL

Wilson Sonsini Goodrich & Rosati,
Professional Corporation
San Diego, California

INDEPENDENT AUDITORS

KPMG LLP
San Diego, California

INVESTOR RELATIONS

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PFEnex